AF/1638

FULBRIGHT & JAWORSKI L.L.P.
A REGISTERED LIMITED LIABILITY PARTNERSHIP
600 CONGRESS AVENUE, SUITE 2400
AUSTIN, TEXAS 78701-3271
WWW.FULBRIGHT.COM

RHANSON@FULBRIGHT.COM
DIRECT DIAL: (512) 536-3085

TELEPHONE: (512) 474-5201
FACSIMILE: (512) 536-4598

December 23, 2003

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37 C.F.R 1.8

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December 23, 2003
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Robert E. Hanson

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: *SN 09/772,520 entitled "PLANTS AND SEEDS OF CORN VARIETY I026458" – by Francis L. Garing; Our Ref. DEKA:276US; Client Ref. [34-63(52321)]*

Commissioner:

Transmitted herewith for filing are:

1. A Supplemental Brief on Appeal (an original and two copies);

2. A Request for Reinstatement of Appeal Under 37 C.F.R. §1.193(b)(2); and

3. A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

Should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski L.L.P. Account No.: 50-1212/DEKA:276US.

Respectfully submitted,

Robert E. Hanson
Reg. No. 42,628

REH/vv
Enclosures: As stated

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December 23, 2003
Date

Robert E. Hanson

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Francis L. Garing

Serial No.: 09/772,520

Filed: January 29, 2001

For: PLANTS AND SEEDS OF CORN VARIETY I026458

Group Art Unit: 1638

Examiner: Mehta, Ashwin D.

Atty. Dkt. No.: DEKA:276US

REQUEST FOR REINSTATEMENT OF APPEAL
UNDER 37 C.F.R. §1.193(b)(2)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

This paper is filed in response to the Office Action mailed on September 23, 2003 in connection with the above-captioned application. A Supplemental Appeal Brief is being filed concurrently herewith.

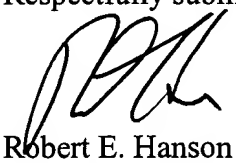
It is believed that no fee is due. However, should any fees be due for any reason in connection with the filing of this document, the Commissioner is authorized to withdraw the appropriate fee from Fulbright & Jaworski L.L.P. Account No.: 50-1212/DEKA:276US.

On January 23, 2003, the Examiner mailed to Applicants a final Office Action. On June 30, 2003, Applicants filed an Appeal Brief. In response to Applicants' Appeal Brief, the Examiner re-opened prosecution and mailed a Third Office Action dated September 23, 2003. The Third Office Action removed a rejection of claim 21 under 35 U.S.C. §112, second paragraph and added rejections of claims 2, 6, 11, 15, 16-20, 22, 28 and 30 for alleged indefiniteness under 35 U.S.C. §112, second paragraph; added rejections of claims 2, 6 and 11 for an alleged lack of written description under 35 U.S.C. §112, first paragraph and added rejections of claims 27-30 under 35 U.S.C. §112, first paragraph for an alleged lack of enablement. The new rejections do not relate to new amendments made by Applicants and thus it is not clear why the rejections were not raised earlier.

Applicants respectfully request that the Appeal be reinstated pursuant to 37 C.F.R. §1.193(b)(2) so that the prosecution of the case may be advanced and the Appeal considered by the Board. A Supplemental Appeal Brief is included herewith.

Should the examiner have any questions regarding this submission, a telephone call to the undersigned is respectfully requested.

Respectfully submitted,



Robert E. Hanson
Reg. No. 42,628
Attorney for Applicant

FULBRIGHT & JAWORSKI, LLP
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 536-3085
(512) 536-4598 (facsimile)

Date: December 23, 2003

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Francis L. Garing

Serial No.: 09/772,520

Filed: January 29, 2001

For: PLANTS AND SEEDS OF CORN VARIETY I026458

Group Art Unit: 1638

Examiner: Mehta, A.

Atty. Dkt. No.: DEKA:276US

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December 23, 2003
Date

Robert E. Hanson

SUPPLEMENTAL BRIEF ON APPEAL

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Francis L. Garing	Group Art Unit: 1638
Serial No.: 09/772,520	Examiner: Mehta, A.
Filed: January 29, 2001	Atty. Dkt. No.: DEKA:276US
For: PLANTS AND SEEDS OF CORN VARIETY I026458	

SUPPLEMENTAL BRIEF ON APPEAL

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby submit an original and two copies of this Supplemental Appeal Brief. This Brief is filed pursuant to the Request For Reinstatement Of Appeal Under 37 C.F.R. §1.193(B)(2) filed concurrently herewith. The date for filing the instant Brief is December 23, 2003, based on the mailing of the Third Office Action withdrawing the case from appeal on October 23, 2003.

The fee for filing this Supplemental Appeal Brief was filed with the first Appeal Brief mailed on June 30, 2003. No additional fees are believed due in connection with the instant paper. However, should any fees be due, the Commissioner is authorized to withdraw the appropriate fee from Fulbright & Jaworski L.L.P. Deposit Account No. 50-1212/DEKA:276US. Please date stamp and return the enclosed postcard to evidence receipt of this document.

I. REAL PARTIES IN INTEREST

The real party in interest is Monsanto Company, the parent company of wholly-owned subsidiary DeKalb Genetics Corporation, the assignee of this application.

II. RELATED APPEALS AND INTERFERENCES

Appeals were filed in U.S. Patent Application Ser. No. 09/772,520; U.S. Patent Application Ser. No. 09/788,334; U.S. Patent Application Ser. No. 09/606,808; U.S. Patent Application Ser. No. 10/077,589; and U.S. Patent Application Ser. No. 10/077,591, which are also directed to inbred corn plants and contain some of the same rejections as in this case and therefore may have a bearing on the Board's decision in the pending appeal.

III. STATUS OF THE CLAIMS

Claims 1-31 were filed with the application and were pending at the time of the final Office Action. Claims 1, 2, 5-13 and 15-20 were allowed in the final Office Action and claims 3, 4, 14, 21 and 24-31 were rejected. After an Appeal by Applicants and filing of an Appeal Brief, the Examiner re-opened prosecution and removed the rejection of claim 21 under 35 U.S.C. §112, second paragraph, and added rejections of claims 2, 6, 11, 15, 16-20, 22, 28 and 30 for alleged indefiniteness under 35 U.S.C. §112, second paragraph; claims 2, 6 and 11 for an alleged lack of written description under 35 U.S.C. §112, first paragraph and claims 27-30 under 35 U.S.C. §112, first paragraph, for an alleged lack of enablement. The rejections were not necessitated by an amendment to the claims and thus the impetus for adding the rejections at this time is unclear to Appellants.

Claim 4 was cancelled in an Amendment Under 37 C.F.R. §1.116 filed with the Appeal Brief on June 30, 2003. The status of the Amendment was not indicated in the Third Office Action and is currently unknown. The appeal of this claim has been withdrawn. No other claims

have been canceled. Claims 1-31 were thus pending prior to the entry of the 116 Amendment and claims 1-3 and 5-31 pending after entry of the Amendment. Claims 2, 3, 6, 11, 14-22 and 24-31 have been rejected and are the subject of the instant appeal. A copy of the appealed claims is attached hereto as Appendix 1 and a copy of the pending claims after entry of the Amendment under 37 C.F.R. §116 is attached as Appendix 2. A copy of the pending claims without the entry of the Amendment is attached as Appendix 3.

IV. STATUS OF AMENDMENTS

An Amendment Under 37 C.F.R. §1.116 was filed with the Appeal Brief on June 30, 2003. The status of the Amendment was not indicated in the Third Office Action and is currently unknown. No other amendments were made subsequent to the final Office Action. The

V. SUMMARY OF THE INVENTION

The invention relates to the novel inbred corn plant designated I026458 and seeds or populations of seed thereof. Specification at page 5, lines 5-22. The invention also relates to single locus converted plants of I026458. Specification at page 6, lines 12-21. The invention further relates to methods for breeding I026458 with other corn plants, and hybrid plants produced thereby. Specification from page 7, line 23 to page 9, line 16.

VI. ISSUES ON APPEAL

(1) Are claims 2, 3, 6, 11, 14-20, 22, 28 and 30 properly rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out the subject matter which applicants regard as the invention?

(2) Are claims 2, 3, 6, 11, 14, 21 and 24-31 properly rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to convey that the applicants were in possession of the claimed invention?

(3) Are claims 27-30 properly rejected under 35 U.S.C. §112, first paragraph, as lacking enablement?

VII. GROUPING OF THE CLAIMS

Claim 2 is directed to a population of seed of the corn variety I026458, whereas claim 3 is directed to an essentially homogeneous population of seed of corn variety I026458 and claim 14 is directed to an essentially homogeneous population of corn plants produced by growing the seed of corn variety I026458. The analysis of issues on appeal for claims 3 and 14 turns on the meaning of "essentially homogeneous," and thus the claims stand or fall together, but separately from claim 2 and the remaining claims, which are directed to distinct subject matter with different issues on appeal. The analysis of claims 6 and 11 turns on the interpretation of the term "in accordance with" and thus these claims stand or fall together but separately from the remaining claims. The rejection of claims 15, 17 and 20 turns on the interpretation of the term "capable of expressing" and thus these claims stand or fall together but separately from the remaining claims. The rejection of claims 16 and 27 turns on whether the claims broaden the scope of the claims from which they depend and thus these claims stand or fall together but separately from the remaining claims. Claims 18, 19, 22, 28 and 30 have been rejected separately for various allegedly indefinite terms and thus these claims stand or fall separately for these rejections. Independent claim 21 is directed to a process of producing corn seed comprising crossing first and second corn plants, whereas claims 24-26 are directed to hybrid plants produced by certain embodiments of this process. Process and product claims present

different issues for the analysis of written description under 35 U.S.C. §112 and thus claims 21 and 24-26 each stand or fall separately from the remaining claims on appeal, while claims 24-26 stand or fall together. Claims 27-30 are directed to a corn plant of variety I026458 which comprises a single locus conversion and, therefore, these claims stand or fall together. Claims 27-30 stand or fall separately from the remaining appealed claims, as the rejection of only these claims centers on whether written description has been provided for a single locus conversion of corn plant I026458, and the issue is distinct from other issues on appeal. Another appealed independent process claim is present in the case in addition to claim 21, claim 31, but comprises a distinct series of steps from claim 21, and thus presents different written description issues on appeal. The claim therefore stands or falls separately from both claim 21 and the remaining claims.

VIII. SUMMARY OF THE ARGUMENT

The Examiner has made 11 separate indefiniteness rejections. The rejections have been made without consideration of the repeated caution by the Federal Circuit that all that is necessary under the second paragraph of §112 is that one of skill in the art understand the metes and bounds of what is being claimed. As set forth individually below, the metes and bounds of the properly construed claims are clear to one of skill in the art.

The written description rejections fail because the claimed subject matter has been fully described. Each of the claimed hybrid plants and seeds having inbred corn plant I026458 as one parent have as half of their genome the same genetic contribution from I026458, given that corn plant I026458 is inbred. This structural characteristic is readily detectable and thus defines the claimed plants. These plants can be produced using any second plant, thus written description with regard to the second parent is satisfied based on the countless corn varieties known to those

of skill in the art, including the more than 300 corn varieties for which utility patents have previously been issued. Methods of crossing the claimed corn variety have been fully described in the recited steps, and such corn breeding steps were well known in the art. Single locus conversions of I026458 were also fully described, in that well more than a representative collection of single locus conversion traits are described in the specification and were well known to those of skill in the art. The single locus conversion traits themselves are further not being claimed, rather it is corn plant I026458 comprising any given single locus conversion that is claimed.

The enablement rejections fail because Appellants working examples and descriptions in the specification fully enable the claimed subject matter. The Examiner has improperly disregarded this evidence and failed to support the rejections in contradiction of the standards of the APA.

IX. ARGUMENT

A. The Rejections Under 35 U.S.C. §112, Second Paragraph, Are Improper

1. Rejection of claim 3

The Examiner rejected claims 3 and 4 as allegedly broadening the claims from which they depend. Claim 4 has been canceled and thus the rejection is now moot. With respect to claim 3, it is noted that the claim does not broaden the scope of the claim from which it depends, claim 2. Claim 2 reads as follows:

> 2. A population of seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

Claim 3 specifies the population of seed of claim 2, "further defined as an essentially homogeneous population of seed." Claim 3 thus further defines the population of claim 2 as

being "essentially homogeneous." While claim 2 is directed to a population of seed of the corn variety I026458, it is not necessary that the population be an essentially homogeneous population of seed. A population may not be essentially homogeneous yet still be a population. For example, the relevant definition of "population" from the on-line version of the Merriam-Webster™ dictionary is "a body of persons or individuals having a quality or characteristic in common." **Exhibit A**. In contrast, the definition for "homogeneous" from the same on-line dictionary is given as "of uniform structure or composition throughout." **Exhibit B**. Therefore a collection of seed may at one time have a quality or characteristic in common, *e.g.*, be of variety I026458, yet not be of uniform structure or composition throughout. For example, a population of seed of corn variety I026458 could be non-uniform in size or shape, due to growth or other conditions, yet still have the common quality of being a corn plant of variety I026458. As such, claim 3 is in proper dependent form and is not indefinite. Reversal of the rejection is thus respectfully requested.

2. Rejection of claim 14

The Examiner has also maintained the rejection of claim 14 as being indefinite for reciting the term "essentially homogeneous population." Claim 14 reads as follows:

> 14. An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

Appellants again note that, as set forth above, a population need not be essentially homogeneous, whether a population of plants or seeds. Further defining a population as essentially homogeneous does not render the claim indefinite. A population of plants grown from the seed of corn variety I026458 could vary in size or other characteristics due to environmental or other conditions, but still constitute a population of corn plant produced by growing the seed of corn variety I026458. As such, "essentially homogeneous" further defines

the scope of the claim and the term as it is used is not indefinite. Reversal of the rejection is thus respectfully requested.

3. Rejection of claim 2

The Examiner rejects claim 2 taking the position that "population of seed of the corn variety I026458" is unclear on the basis that an express definition is not provided for "population" and based on a citation the Examiner makes to a particular use of the term in the specification. In response, Appellants note that the term "population" has a well known meaning in the art and thus the use of the term in the claims is not indefinite. Claim terms are given their plain meaning and limitations from the specification are not read into a claim. Provided herewith as evidence of the well known meaning of "population" is a copy of the definition for this term from the on-line version of the Merriam-Webster™ dictionary. **Exhibit A**. The term is therefore fully definite and removal of the rejection is respectfully requested.

4. Rejection of claims 6 and 11

The Action states that "in accordance with" renders the claim indefinite because the meaning of the term is not exactly clear. In response, Appellants note that the term has a well known meaning in the art. As evidence of the meaning, Appellants have attached hereto the dictionary definition for "accordance" from the on-line version of the Merriam-Webster™ dictionary. (**Exhibit C**). As can be seen, the definition given is "agreement, conformity." The example sentence given in the definition is "in accordance with a rule" The Examiner has provided no basis to conclude why the claim would be indefinite in view of this well known meaning. The use of the term in the claim is thus not indefinite and removal of the rejection is respectfully requested.

5. Rejection of claims 15, 17 and 20

The Examiner rejects claims 15, 17 and 20 for use of the term "capable of expressing." In particular, it is stated that it is unclear if the plant actually expresses the trait. Appellants note that the term "capable" is well know in the art and thus the claim is fully definite. Claim breadth is not indefiniteness. One of skill in the art would understand whether a corn plant is capable of expressing all of the traits of corn plant I026458 because Appellants have provided the corn plant I026458 by way of a biological deposit with the ATCC. One of skill in the art would therefore readily ascertain whether a plant is capable of expressing all of the traits of I026458 based on direct comparisons. Because the standard is readily ascertainable, the use of the limitation in the claims is not indefinite. Reversal of the rejection is therefore respectfully requested.

6. Rejection of claims 16 and 27

The Action rejects the claims as allegedly broadening the scope of the claims from which they depend. It is in particular stated that the claims "add on a gene or locus to the genome of the plant of their parent claims" and that there is no indication how the plants acquired the gene and that the gene is not possessed by the plant of the parent claims.

Appellants do not understand the rejection. As stated in the sentences explaining the rejection, the claims further narrow the claim from which they depend because the claims specify a further limitation ("add on a gene"), and the limitation is not possessed by the parent claims. Specifically, claims 16 adds "a nuclear or cytoplasmically-inherited gene conferring male sterility," while claim 27 adds "a single locus conversion," neither element of which is required by the main claim. Therefore, both claims (1) ***contain a reference to parent claim*** from which they depend, (2) contain a ***further limitation*** of the subject matter claimed in the main claim, and (3) ***incorporate all elements*** of the claim from which they depend. The claims are therefore in proper dependent form pursuant to 37 C.F.R. §1.75(c) and are fully definite. As to how the

plants acquire the added elements, this is irrelevant to the scope or definiteness of the claims, as the claims are product claims, not process or product by process claims. Reversal of the rejection is therefore respectfully requested.

7. Rejection of claim 18

The Action rejects claim 18 taking the position that "derived from" in the recitation "wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks" is indefinite.

Appellant note that the term is fully definite based on the well known meaning of "derived." For example, the relevant dictionary definitions for "derived" from the on-line version of the Merriam-Webster™ dictionary are "**1 a :** to take, receive, or obtain especially from a specified source **b :** to obtain (a chemical substance) actually or theoretically from a parent substance." **Exhibit D**. Both definitions indicate that in this case the regenerable cells are obtained from the relevant compositions. Given the well known meaning, there is nothing indefinite in the recitation of the term in the claims. Reversal of the rejection is therefore respectfully requested.

8. Rejection of claim 19

The Action rejects claim 19 for use of the term "the regenerable cells comprise protoplasts" because it is stated that protoplasts are not cells. However, Appellants note that the relevant dictionary definition from the on-line version of the Merriam-Webster™ dictionary for "protoplast" is "a plant cell that has had its cell wall removed." **Exhibit E**. A cell may therefore be a protoplast, although its cell wall has been removed. In view of this, the recitation of "cells

are in the form of protoplasts" is not indefinite. Reversal of the rejection is therefore respectfully requested.

9. Rejection of claim 22

The Action rejects claim 22 as allegedly being improperly dependent on claim 21 for not further limiting this claim. This is incorrect. Claim 22 specifies that corn plant I026458 is crossed to a second, distinct inbred corn plant, whereas claim 21 is not so limited. In claim 21, I026458 may be crossed to a second plant that is not distinct from I026458 and is not inbred. In claim 22, I026458 must be crossed to a second, distinct inbred corn plant. Claim 22 therefore further narrows claim 21 and is in proper dependent form. The rejection of the Examiner is thus not understood. Reversal of the rejection is therefore respectfully requested.

10. Rejection of claim 28

The Action states that claim 28 is indefinite because the article "a" in the recitation "wherein the single locus was stably inserted into a corn genome" renders the claim indefinite regarding whether the single locus was inserted into the genome of I026458 or that of a different plant.

The single locus referred to in claim 28 may or may not have been directly inserted into the genome of the claimed plant. This does not render the claim indefinite, however. The single locus may have been inserted into a parent I026458 plant selfed to produce the claimed plant. The claim specifies that the single locus was stably inserted into a corn genome. Loci that are stably inserted into a corn genome are also stably inherited. Thus the single locus need not have been inserted into the genome of corn variety I026458. As such, the metes and bounds of the claim are clear and the claim is not indefinite. Reversal of the rejection is therefore respectfully requested.

11. Rejection of claim 30

The Action rejects claim 30 for use of the terms "yield enhancement," "improved nutritional quality," and "enhanced yield stability." However, the terms are all understood by those of skill in the art and there is no prohibition upon the use of relative terms. The terms must be read in the context of the claim in which they are found. The subject claim recites a single locus that confers the traits of yield enhancement, improved nutritional quality, and enhanced yield stability. It is thus understood the enhancement of yield or yield stability and improved nutritional quality is relative to a plant lacking the single locus. The metes and bounds of the claim are thus fully understood by one of skill in the art and the use of the terms is not indefinite. Reversal of the rejection is therefore respectfully requested.

B. The Written Description Rejection of Claims 2, 3, 6, 11, 14, 21 and 24-31 Is Improper

1. Populations of seed and plants grown therefrom recited in claims 2, 3 and 14 have been fully described

The Action rejects claims 2 and 3 as allegedly not having been adequately described.

Claim 2 reads as follows:

> 2. A population of seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3224.

Claim 3 reads as follows:

> 3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

Claim 2 finds literal support in the deposit of seed made with the ATCC and thus the rejection is not understood. Specifically, Appellants have deposited a population of 2500 seeds with the ATCC, fully supporting the claim. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d

1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). With regard to claim 3, as set forth above, this is a proper dependent claim that further defines claim 2. This is because a population, which is a group of individuals sharing a common characteristic, need not be substantially homogeneous. This also has literal support in the recited seed deposit as claim 2, as an essentially homogeneous population may be prepared, for example, by selecting seeds from the population of claim 2 having shared selected characteristics, for example, seed weight, seed size or seed shape. Claim 14, directed to an essentially homogeneous population of corn plants produced by growing the seed of the corn variety I026458, has similarly been described. As indicated above, "essentially homogeneous" properly modifies "population." The Examiner has not alleged that populations of corn plants produced by growing the seed of the corn variety I026458 have not been described. Reversal of the rejections is thus respectfully requested.

2. The marker profiles in claims 6 and 11 have been described

The Action rejects claims 6 and 11 because it is stated that written description for the markers named in Tables 6 and 7 has not been provided. Initially, it is noted that no basis for this allegation has been provided. The profiles are recited in the tables and the claims claim nothing more than what is provided in Tables 6 and 7. Literal support is therefore found in the specification.

With regard to the markers themselves, the SSR markers were from Celera AgGen, Inc., which provides a commercial service for genotyping of maize varieties. Nothing is therefore indefinite about the recitation of the marker phenotypes. With regard to the isozymes, the markers are well known and isozyme analysis in general very well known having been used for decades. The claimed subject matter has therefore been fully described.

3. Hybrid plants recited in claims 22-24 have been fully described

a. The claimed hybrid plants share the genetic complement of corn variety I026458

Rejected claims 22-24 are directed to hybrid plants and seeds produced with corn plant I026458 as one parent. Appellants have fully described this claimed subject matter in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. As set forth in the breeding history at pages 26-27 of the specification, corn plant I026458 is an inbred corn plant. All of the claimed hybrid plants having I026458 as a parent will therefore contain a copy of the same genome as corn plant I026458. That is, because I026458 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant I026458, save the possibility of the rare spontaneous mutation or undetected segregating locus. This entire genetic contribution of corn plant I026458 is described in the specification by way of the deposit of seed of corn plant I026458 with the ATCC. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). This represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants in full compliance with the written description requirement.

The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus,*

visualize or recognize the identity of the members of the genus" (emphasis added)). Here, all of the members of the claimed genus of hybrids having I026458 as one parent share the structural feature of having the genetic complement of I026458. One of skill in the art could thus readily identify the members of the genus. The written description requirement has, therefore, been fully complied with.

b. The entire genetic complement of variety I026458 is described by way of the proffered deposit of seed

Appellants describe the entire genetic sequence of corn variety I026458 by way of the biological deposit of seed with the ATCC. In particular, the Federal Circuit has recently held that a biological deposit may be used to satisfy written description for nucleic acids, whether the nucleic acid sequence is set forth in the specification or not. In *Enzo Biochem, Inc. v. Gen-Probe Inc.*, the patent owner had deposited six strains of *N. gonorrhoeae* and claimed nucleotide sequences hybridizing to the nucleic acids of these strains, but the patent application did not set forth the nucleic acid sequences of these strains in the specification. 296 F.3d 1316, 1328 (Fed. Cir. 2002). The Federal Circuit nonetheless held that "as those bacteria were deposited, their ***bacterial genome is accessible*** and, under our holding today, they are ***adequately described in the specification by their accession numbers***." (emphasis added) *Id.* In its holding, the Federal Circuit considered the burden that would be placed on applicants were they required to sequence each of the strains, noting lower court findings that it would have taken 3,000 scientists a month to sequence the bacterial genome of one strain of *N. gonorrhoeae*. *Id.* In the instant case, even more effort would be required, as corn is a higher life form with a more complex genome than the bacteria deposited in *Enzo*. The Examiner would nonetheless appear to require this much of Appellants in direct contradiction of *Enzo*.

c. The Examiner Incorrectly States the Holding of *Enzo*

The Examiner attempted to counter the showing by Appellants that the holding of *Enzo* establishes a written description for the genome of corn variety I026458 by stating that *Enzo* is inapplicable because in that case a function was correlated with the deposited product. However, this constitutes a misstatement of the holding of *Enzo* that obfuscates the legal principle for which the case stands. First, the alleged "function" in *Enzo* was the ability to hybridize to the deposited sequences. *Enzo*, 296 F.3d at 1323. This is in reality no function at all, but rather is a structural limitation, given that only sequences with a given degree of homology will hybridize. Second, the question in *Enzo* was not whether a function had to be disclosed in order to have adequate written description for a claimed sequence, rather it was whether a sequence could be claimed by way of a function when it was described in the specification only by way of a deposit. This is illustrated by the statement of issues presented made by the Federal Circuit:

> we first inquire whether Enzo's deposits of the claimed nucleotide sequences of claims 4 and 6 may constitute an adequate description of those sequences. Secondly, we will consider whether the description requirement is met for all of the claims on the basis of the functional ability of the claimed nucleotide sequences to hybridize to strains of *N. gonorrhoeae* that are accessible by deposit.
>
> *Id.* at 1325.

These are distinct issues. To the first question, the Federal Circuit expressly stated that a deposit constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, P 1. Specifically the court stated"[w]e therefore agree with Enzo that reference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement." *Id.* at 1326. The Federal Circuit did not make or condition this holding on a function that was disclosed. The question was whether the deposit satisfied written description for the claimed nucleic acid sequences, which the court held that it did. There is, therefore, no

basis to conclude that the holding in *Enzo* does not demonstrate that Appellants have provided a written description of the entire genetic complement of corn variety I026458 based on the deposit with the ATCC.

d. The shared characteristics of the claimed hybrid plants are readily identified and described in the specification

As set forth above, the claimed F1 hybrid plants having I026458 as one parent will share the same genetic complement received from I026458. This is readily identifiable by genetic marker analysis, as shown in Tables 6 and 8 of the specification. There shown is the SSR genetic marker profile of corn variety I026458, as well as an the exemplary hybrid plant designated 7041221 that was made using I026458 as one parent. As can be seen, hybrid corn plant 7041221 has the SSR genetic marker profile of I026458, and also includes the genetic markers from the second parent plant used to make the hybrid. The same will be true for any other hybrid plant having I026458 as one parent, save for an occasional difference at a locus due to spontaneous genetic rearrangements, which occur at statistically insignificant frequencies in essentially all organisms.

The second plant that is used to make the claimed hybrid plants is irrelevant, as a hybrid will be produced any time corn plant I026458 is crossed with a second plant. That is, any second plant capable of reproduction may be used to make the hybrid plant. Appellants cannot therefore be said to lack written description for the second genetic complement. This is particularly so given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing of the instant application, each of which could be crossed to make a hybrid plant within the scope of the claims. This is evidenced by a review of the U.S.P.T.O. patent data website, which reveals utility patents issued on hundreds of different corn varieties. Any one of these corn plants, or the many hundreds or thousands of other maize plants

that were known at the time the application was filed, could be used to produce an F1 hybrid plant having corn variety I026458 as one parent, and each of these would share the genetic complement of I026458.

Written description is reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The specification need not disclose what is well-known to those skilled in the art and preferably omits what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). As ***any*** different second plant may be used to produce the claimed hybrid plants and such plants were well known to those of skill in the art, Appellants cannot be said to have not been in possession of the second parent plant. The claimed hybrid corn plants have therefore been described in compliance with 35 U.S.C. §112, first paragraph.

The Action attempts to downplay the significance of the genetic marker data given in the specification by stating that some loci may be shared by other plants, that primer sequences are not described or that certain isozyme markers are not informative. However, no effort has been made to show that any substantial number of marker loci actually *are* shared by other plants. Further, Appellants do not claim such "other" plants, so this is irrelevant to written description. No basis has been provided to conclude that the claimed hybrid plants are not distinct and clearly identifiable by the genetic marker profile that has been set forth. Regarding the availability of genetic markers, the service that was used to detect SSR markers is commercially available to the public. Further, SSR and any of the other genetic marker systems that are well known to those of skill in the art may potentially be used, as is described on pages 60-61 of the specification. Regardless of whether SSR markers are used, the shared genetic complement of the claimed hybrid plants having corn variety I026458 as one parent distinguishes them. As the entire

genome of corn variety I026458 has been described, at least, by way of the seed deposit that has been made, any polymorphic locus could be used including or in addition to the SSR markers shown in Tables 6 and 8.

e. The Examiner's allegations that the expression of the genetic complement of corn variety I026458 is unpredictable are inapposite

The Examiner alleges that claimed hybrid plants have not been described despite inheriting the genetic complement of variety I026458 because information is not provided regarding the morphological and physiological traits of the hybrid plants. It is alleged that how the genes that are inherited would be expressed or would interact has not been shown. However, this misses the point that Appellants have gone one step further than morphological and physiological traits by describing the claimed hybrid plants at the genetic level. A better description could not be made than at the genetic level. Morphological and physiological traits, while helpful, are also subject to environmental variation and require subjective gradations. Genetic testing goes to the source of traits and yields concrete values.

The law further makes no distinctions regarding the manner in which Appellants choose to describe claimed compositions. Rather, an applicant must merely describe the claimed subject matter by "whatever characteristics sufficiently distinguish it." *Amgen v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Here, Appellants have described the genetic complement of parent plant I026458 that will be comprised in the claimed hybrid plants. This has been achieved using the SSR and isozyme genetic marker profiles given in tables 6-9 of the specification. Indeed, Appellants describe the entire genetic complement of parent plant I026458 by way of a seed deposit made with the ATCC. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002).

f. Appellants fully describe an exemplary hybrid made using inbred I026458

Further description of claimed hybrid plants is also provided in the specification by way of a detailed description of hybrid 7041221, which was produced with I026458 as one inbred parent. This plant is representative of hybrids produced using I026458 as one parent, each of which comprise the genetic complement of the parent corn plant as set forth above. Table 4 of the specification gives the performance characteristics for 7041221 and provides comparisons against other hybrid varieties. In Table 5, the morphological traits of 7041221 are given. The SSR and isozyme marker profiles for hybrid 7041221 are given in Tables 8 and 9, respectively. This information, combined with the descriptions of I026458 in the specification and the shared structure among hybrids having corn plant I026458 as a parent, is more than adequate to describe the claimed subject matter.

4. Single locus converted plants of corn variety I026458 have been fully described

The Examiner has maintained the rejection of claims 27-30, which are directed to a single locus conversion of corn plant I026458. In particular, the Examiner has alleged that: (1) the characteristics of the claimed single locus converted plant are unpredictable and/or not described, (2) the claims encompass genes that have yet to be discovered, and (3) the sequences and/or sources for the numerous examples of single locus traits disclosed in the application have not been described.

a. The claimed subject matter is not unpredictable

With regard to the first point made by the Examiner, it is noted that a "single locus converted (conversion) plant" is defined at page 23, lines 6-12 of the specification as follows:

> [p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics

> conferred by the single locus transferred into the inbred *via* the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Therefore, the claimed plants comprising a single locus conversion possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]". The Examiner's comments with regard to various allegedly unknown characteristics are thus outside the scope of the claims. With regard to the claimed subject matter, Appellants have more than adequately described such a plant that comprises essentially all of the desired morphological and physiological characteristics of corn plant I026458 by way of the description and deposit of I026458 alone, not to mention other description provided. To hold otherwise would be to limit Appellants to that subject matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)) .

b. The Examiner has applied the written description requirement with respect to unclaimed subject matter

With respect to the Examiner's allegation that the claims encompass genes that have yet to be discovered, it is noted that Appellants ***do not claim undiscovered genes***. The claimed subject matter is the corn variety I026458 comprising a single locus conversion. Any single locus conversion may be introduced into corn variety I026458 to produce the claimed single locus conversion. The fact that a given gene could be isolated in the future and introduced as a single locus conversion is irrelevant – the new gene is not claimed *per se*, a single locus conversion of corn plant I026458 is claimed. Under the reasoning of the Examiner, essentially

any claim could be read to encompass subject matter yet to be invented and therefore not be described. A claim to a corn plant transformed with a *Bacillus thuringiensis* gene would be invalid because it would encompass corn varieties yet to be discovered. A claim to a given gene operably linked to a regulatory element would be invalid because as yet to be isolated regulatory elements would be encompassed. Nearly any biotechnological invention could be viewed this way applying the Examiner's reasoning. However, it is not any given single locus that is claimed, it is a corn plant of corn variety I026458 which comprises a single locus that has been claimed.

c. Appellants have disclosed numerous single locus traits and such traits were well known to those of skill in the art when the application was filed

The Examiner alleges that the traits recited in the application and referred to in Appellants previous response to office action have not been shown to have been known in the art. The Examiner has therefore invited Appellants to amend the claims to recite individual examples of single locus traits provided the prior art teaches that those types of genes have been isolated and therefore reduced to practice. However, the Examiner has ignored Appellants previous evidence submitted in the prior response to office action and also recited in the specification showing numerous single locus traits that were described.

Among just the examples in the specification recited with a publication reference or patent number are the following (see specification at pages 30-35): genes conferring male sterility (U.S. Patent No. 3,861,709, U.S. Patent No. 3,710,511, U.S. Patent No. 4,654,465, U.S. Patent No 5,625,132, and U.S. Patent No. 4,727,219, incorporated by reference); male-sterility restorer genes (U.S. Patent Nos. 5,530,191, 5,689,041, 5,741,684, and 5,684,242, incorporated by reference); a herbicide resistant EPSPS mutation termed *aroA* (U.S. Patent 4,535,060); and a

mutant maize gene encoding a protein with amino acid changes at residues 102 and 106 (PCT Publication WO 97/04103).

The single locus traits are also described by way of PCT Application Publ. WO 95/06128, which was specifically incorporated by reference at page 31 of the specification. Examples of some of the single locus traits described in WO 95/06128, including any associated phenotype and publication reference given, are as follows:

the uidA gene from *E. Coli* encoding β-glucuronidase (GUS) (cells expressing *uidA* produce a blue color when given the appropriate substrate, Jefferson, R.A. 1987. *Plant Mol. Biol. Rep* 5: 387-405); the *bar* gene from *Streptomyces hygroscopicus* encoding phosphinothricin acetyltransferase (PAT) (cells expressing PAT are resistant to the herbicide Basta, White, J., Chang, S.-Y.P., Bibb, M.J., and Bibb, M.J. 1990. *Nucl. Ac. Research* 18: 1062); the *lux* gene from firefly encoding luciferase (cells expressing *lux* emit light under appropriate assay conditions, deWet, J.R., Wood, K.V., DeLuca, M., Helinski, D.R., Subramani, S. 1987. *Mol. Cell. Biol.* 7: 725-737); the *dhfr* gene from mouse encoding dihydrofolate reductase (DHFR) (cells expressing *dhfr* are resistant to methotrexate; Eichholtz, D.A., Rogers, S.G., Horsch, R.B., Klee, H.J., Hayford, M., Hoffman, N.L., Bradford, S.B., Fink, C., Flick, J., O'Connell, K.M., Frayley, R.T. 1987. *Somatic Cell Mol. Genet.* 13: 67-76); the *neo* gene from *E.Coli* encoding aminoglycoside phosphotransferase (APH) (cells expressing *neo* are resistant to the aminoglycoside antibiotics; Beck, E., Ludwig, G., Auerswald, E.A., Reiss, B., Schaller, H. 1982. *Gene* 19: 327-336); the *amp* gene from *E. Coli* encoding β-lactamase (cells expressing β-lactamase produce a chromogenic compound when given the appropriate substrate; Sutcliffe, J.G. 1978. *Proc. Nat. Acad. Sci.* USA 75: 3737-3741); the *xylE* gene from *Ps. putida* encoding catechol dihydroxygenase (cells expressing *xylE* produce a chromogenic compound when given the appropriate substrate; Zukowsky *et al.* 1983. *Proc. Nat. Acad. Sci.* USA 80: 1101-1105); the R,C1 and B genes from maize encode proteins that regulate anthocyanin biosynthesis in maize (Goff, S., Klein, T., Ruth, B., Fromm, M., Cone, K., Radicella, J., Chandler, V. 1990. *EMBO J.:* 2517-2522); the ALS gene from *Zea mays* encoding acetolactate synthase and mutated to confer resistance to sulfonylurea herbicides (cells expressing ALS are resistant to the herbicide; Gleen. Yang, L.Y., Gross, P.R., Chen, C.H., Lissis, M. 1992. *Plant Molecular Biology* 18: 1185-1187); the proteinase inhibitor II gene from potato and tomato (plants expressing the proteinase inhibitor II gene show increased resistance to insects; potato - Graham, J.S., Hall, G., Pearce, G., Ryan, C.A. 1986 *Mol. Cell. Biol.* 2: 1044-1051; tomato - Pearce, G., Strydom, D., Johnson, S., Ryan, C.A. 1991. *Science* 253: 895-898); the *Bt* gene from *Bacillus thuringensis* berliner 1715 encoding a protein that is toxic to insects (this gene is the coding sequence of *Bt* 884 modified in two regions for improved expression in plants; Vaeck, M., Reynaerts, A., Hofte, H., Jansens, S., DeBeuckeleer, M., Dean, C., Aeabeau, M., Van Montagu, M., and Leemans, J. 1987. *Nature* 328: 33-37); the *bxn* gene from *Klebsiella ozaeneae* encoding a nitrilase enzyme specific for the herbicide bromoxynil (cells expressing this gene are resistant to the herbicide bromoxynil; Stalker, D.m., McBride, K.E., and Malyj, L. *Science* 242: 419-422, 1988); the WGA-A gene encoding wheat germ agglutinin (expression of the WGA-A

gene confers resistance to insects; Smith, J.J., Raikhel, N.V. 1989. *Plant Mol. Biology* 13: 601-603); the *dapA* gene from *E. coli* encoding dihydrodipicolinate synthase (expression of this gene in plant cells produces increased levels of free lysine; Richaud, F., Richaud, C., Rafet, P. and Patte, J.C. 1986. *J. Bacteriol.* 166: 297-300); the *Z10* gene encoding a 10kd zein storage protein from maize (expression of this gene in cells alters the quantities of 10kD Zein in the cells; Kirihara, J.A., Hunsperger, J.P., Mahoney, W.C., and Messing, J. 1988. *Mol. Gen. Genet.* 211: 477-484); the Bt gene cloned from *Bacillus thuringensis* Kurstaki encoding a protein that is toxic to insects (the gene is the coding sequence of the cry IA(c) gene modified for improved expression in plants - plants expressing this gene are resistant to insects; Höfte, H. and Whiteley, H.R., 1989. *Microbiological Reviews.* 53: 242-255); the ALS gene from *Arabidopsis thaliana* encoding a sulfonylurea herbicide resistant acetolactate synthase enzyme (cells expressing this gene are resistant to the herbicide Gleen. Haughn, G.W., Smith, J., Mazur, B., and Somerville, C. 1988. *Mol. Gen. Genet.* 211: 266-271); the *dehl* gene from *Pseudomonas putida* encoding a dehalogenase enzyme (cells expressing this gene are resistant to the herbicide Dalapon; Buchanan-Wollaston, V., Snape, A., and Cannon, F. 1992. *Plant Cell Reports* 11: 627-631); the hygromycin phosphotransferase II gene from *E. coli* (expression of this gene in cells produces resistance to the antibiotic hygromycin. Waldron, C., Murphy, E.B., Roberts, J.L., Gustafson, G.D., Armour, S.L., and Malcolm, S.K. *Plant Molecular Biology* 5: 103-108, 1985); the *mtlD* gene cloned from *E. coli* (the gene encodes the enzyme mannitol-1-phosphate dehydrogenase; Lee and Saier, 1983. *J. of Bacteriol.* 153:685); the HVA-1 gene encoding a Late Embryogenesis Abundant (LEA) protein (the gene was isolated from barley; Dure, L., Crouch, M., Harada, J., Ho, T.-H. D. Mundy, J., Quatrano, R, Thomas, T, and Sung, R., *Plant Molecular Biology* 12: 475-486.

The foregoing represent just some of the single locus coding sequences that were known as of March 2, 1995; ***nearly six years prior*** to the filing of the instant application. More than 25 regulatory elements were also described therein, as were numerous transformation vectors comprising combinations of these elements. Appellants could describe many more examples of single locus traits that were well known as of the filing date, and would be glad to do so should the Board find it useful. It thus goes without saying that single locus traits were more than well known to those of skill in the art as of the filing date and were fully described in the specification.

Techniques for the introduction of single locus traits by genetic transformation were further well known to those of skill in the art. Some of the transformation methods for corn that were well known as of the filing date and cited in the specification include the following: electroporation (U.S. Patent No. 5,384,253), microprojectile bombardment (U.S. Patent No.

5,550,318; U.S. Patent No. 5,736,369, U.S. Patent No. 5,538,880; and PCT Publication WO 95/06128), *Agrobacterium*-mediated transformation (U.S. Patent No. 5,591,616 and E.P. Publication EP672752), direct DNA uptake transformation of protoplasts (Omirulleh *et al.*, 1993) and silicon carbide fiber-mediated transformation (U.S. Patent No. 5,302,532 and U.S. Patent No. 5,464,765). Introduction of such traits by conventional breeding was also known. In fact, this is one of the most fundamental procedures in agricultural science, and it has not been alleged that this has not been described.

Appellants have therefore shown possession of the claimed single locus conversions. Both large numbers of single locus traits and the associated phenotypes were well known to those of skill in the art. The specification itself defines a single locus converted plant as comprising essentially all of the desired morphological and physiological characteristics of the starting non-converted plant, *e.g.*, I026458. Well more than an adequate number of examples have been provided and were known in the art to satisfy written description. The state of the art must be considered in the written description determination. As such, Appellants respectfully request reversal of the rejection.

5. The rejection of claim 31 has been improperly issued and maintained

a. The Examiner has failed to adequately support the rejections

Claim 31 is a process claim that involve crossing corn variety I026458 according to the specified steps. It is believed that the position of the Examiner is that written description must be provided for each intermediate product in a method claim in the same manner as if the particular product was individually claimed as a composition of matter. That is, Appellants understand that the position taken is that it is not sufficient to describe all of the starting materials for a process and all of the steps carried out on the starting materials, but rather that the structural characteristics of any product made at any intermediate or penultimate step must be described as

if claimed as a composition of matter. Appellants submit that this is a misstatement of the law and, more significantly, note that this rejection has not been adequately set forth on the record. No reasonable basis in law or fact has been given for maintaining the rejection, as the Examiner's arguments appear to be entirely directed to composition of matter claims.

The Examiner cites for "authority" supporting the novel legal position taken in the rejection of claim 31 the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. Sec. 112, ¶'Written Description' Requirement; Request for Comments, 64 Fed. Reg. 71427, 71428 (1999), comment no. 4. Written Description Guidelines, Fed. Reg. Vol. 64, pp 71427, 71428 (1999), comment 4. Third Office Action at p.17, second full paragraph. Specifically, it is stated that "application of the written description guidelines to methods have been adapted." However, the Examiner misconstrues this section. The cited portion states the following:

> (4) Comment: Six comments were in favor of including process and product-by-process claims in the analysis, whereas one comment was opposed. One comment criticized the Guidelines for failing to acknowledge the ``safe harbor" product-by-process type claim noted in Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993), and Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). One comment observed that process and product-by- process claims tend not to implicate many written description issues, and it may be useful to point out possible enablement deficiencies for such claims. Two comments suggested that the Guidelines should distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those where patentability rests in the steps of the process itself. Response: The suggestion to address process and product-by-process claims has been adopted. Furthermore, the training materials will analyze claims wherein the patentability depends on the compositions used therein, as well as those where the patentability rests in the process steps themselves. Enablement issues raised by process and product-by-process claims are outside the scope of these Revised Interim Guidelines.

Appellants find no support in this comment for the position taken. All that the note says is that the Written description Guidelines ***will address*** process and product-by-process claims, *e.g.*, this will be done some time in the future. Indeed the comment appears to indicate that composition

and methods claims will be treated differently, as immediately prior to the sentence indicating that the suggestion will be adopted it is stated that a request was made to "distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those where patentability rests in the steps of the process itself."

Quite tellingly, the Examiner has failed to cite the actual Guidelines themselves in which the issue reserved in the passage of the Interim Guidelines was apparently to be addressed. Appellants direct the Board to the Written Description Guidelines, Fed. Reg. Vol. 66, pp1099-1111 (Jan. 5, 2001). The analysis of written description set forth under these Guidelines involves "(i) Determin[ing] whether the application as filed describes the complete structure (***or acts of a process***) of the claimed invention as a whole." Fed. Reg. Vol. 66, pp1106 (emphasis added). In the next step of the process, the Guidelines state that: "ii) If the application as filed does not disclose the complete structure (***or acts of a process***) of the claimed invention as a whole, determine whether the specification discloses other relevant identifying characteristics sufficient to describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicant was in possession of the ***claimed invention***." *Id.* (emphasis added). These sections clearly demonstrate that the Guidelines distinguish product and process claims. This also illustrates that the Examiner has failed to apply the Guidelines by not considering written description with regard to the claimed invention.

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko,* 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside*, 203 F.3d

1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. As set forth above, the current rejections are unsupported in fact or law. The standards of the APA have therefore not been met and reversal of the rejection is thus respectfully requested.

b. The rejection of claim 31 is contrary to Federal Circuit precedent

As set forth above, it is believed that the rejection is made based on the position that each product produced at any intermediate or penultimate step of the method must be described as if claimed *per se*. However, what is required to meet the written description requirement is that an Applicant show that he or she was in possession of the ***claimed invention***. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Here, a process is claimed, not a product of a process, and thus the steps of that process must be described, not intermediate or final products of the steps. The starting materials for the process must also be provided, otherwise the process could not be completed. However, the only starting materials required are corn variety I026458, which the Examiner does not allege to have not been described, and ***any*** second corn plant. As set forth above, corn plants were well known, and this has also therefore been fully described.

With respect to the steps, these have been fully set forth in the claim. It has not been alleged that any essential steps are absent. All that is required to complete the claimed method is to cross the corn variety I026458 or a product that is produced by any preceding step according to the steps given. All of the starting products for any step within the method are either (1) corn variety I026458, (2) any second corn plant, or (3) a corn plant that is produced by following a preceding method step. The method has therefore been fully described.

It is also noted that corn breeding is well known to those of skill in the art. Without it, there would not be commercial corn varieties, which are typically sold as hybrids produced by crossing two inbred varieties. This is evidenced by the more than 300 issued patents to inbred maize varieties discussed above, given that inbred plants are not produced without multiple generations of intentional self-fertilization. All of the steps recited in claim 31 are typical of the process used for the production of new corn varieties, save for the point of novelty, corn variety I026458. This is evidenced in the breeding history for the production of corn variety I026458, which is given in the specification. The specification also describes methods and considerations for producing new corn varieties in the review of related art, for example, at pages 2-4 of the application.

In conclusion, the claimed subject matter has been fully described. Reversal of the rejections under 35 U.S.C. §112 for an alleged lack of written description is thus respectfully requested.

C. Rejection of Claims Under 35 U.S.C. §112, First Paragraph - Enablement

The Examiner ejects claims 27-30 under 35 U.S.C. §112, first paragraph as allegedly not enabled. The rejected claims are directed to corn plants of the claimed variety comprising a single locus conversion. The rejected claims are directed to corn plants of variety I026458 comprising a single locus conversion. In an attempt to support the rejection, the Action cites several references alleged to show the difficulty of making male sterile or single locus converted plants. However, no basis has been given to show that these references have any relevance to *corn* plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. No showing has been made that the references apply to corn plants absent personal opinion. The

relevance of the references to the claimed invention has therefore not been established as is specifically required to establish a *prima facie* case of non-enablement.

The Examiner has further disregarded Appellants example of a conversion that has been made with a proprietary corn variety by stating that information has been left out, such as the number of crosses that were performed at each step. This is incorrect. The breeding history of the conversion that was made is given. In the breeding history, seven backcrosses are described. No steps are left out and no basis has been provided to demonstrate why this example does not demonstrate enablement for the instant variety.

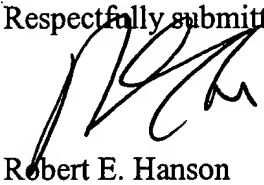
It appears that the Action has improperly placed the burden to show enablement on Appellants. The indication that the references concerning petunias, sugar beets and tomatoes apply to corn is made without any support. At the same time, the Action attempts to require Appellants to show why this is not true. Appellants respectfully note that it is the ***Office*** the bears the burden of supporting its rejections. Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko,* 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. The current rejections are unsupported as required by the APA and contrary to the evidence submitted by Appellants.

In view of the foregoing reversal of the rejection is respectfully requested.

X. CONCLUSION

It is respectfully submitted, in light of the above, none of the pending claims lack written description. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,



Robert E. Hanson
Reg. No. 42,628
Attorney for Appellants

FULBRIGHT & JAWORSKI L.L.P
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 536-3085

Date: December 23, 2003

APPENDIX 1: APPEALED CLAIMS FOLLOWING ENTRY OF THE AMENDMENT UNDER 37 C.F.R. §1.116

2. A population of seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

6. The corn plant of claim 5, having:

(a) an SSR profile in accordance with the profile shown in Table 6; or

(b) an isozyme typing profile in accordance with the profile shown in Table 7.

11. The plant part of claim 10, wherein said cell is further defined as having :

(a) an SSR profile in accordance with the profile shown in Table 6; or

(b) an isozyme typing profile in accordance with the profile shown in Table 7.

14. An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.

17. A tissue culture of regenerable cells of a plant of corn variety I026458, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

18. The tissue culture of claim 17, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

19. The tissue culture of claim 18, wherein the regenerable cells comprise protoplasts or callus cells.

20. A corn plant regenerated from the tissue culture of claim 17, wherein the corn plant is capable of expressing all of the physiological and morphological characteristics of the corn variety designated I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

21. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein one or both of the first or the second parent corn plant is a plant of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228, wherein seed is allowed to form.

22. The process of claim 21, further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein the first or second inbred corn plant is a plant of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

24. Hybrid corn seed produced by the process of claim 23.

25. A hybrid corn plant produced by growing a seed produced by the process of claim 23.

26. The hybrid corn plant of claim 25, wherein the plant is a first generation (F_1) hybrid corn plant.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

29. The corn plant of claim 27, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I026458, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I026458 by crossing a plant of the corn variety I026458 with a second corn plant, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I026458.

APPENDIX 2: PENDING CLAIMS FOLLOWING ENTRY OF THE AMENDMENT UNDER 37 C.F.R. §1.116

1. A seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

2. A population of seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

5. A corn plant produced by growing a seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

6. The corn plant of claim 5, having:
   (a) an SSR profile in accordance with the profile shown in Table 6; or
   (b) an isozyme typing profile in accordance with the profile shown in Table 7.

7. A plant part of the corn plant of claim 5.

8. The plant part of claim 7, further defined as pollen.

9. The plant part of claim 7, further defined as an ovule.

10. The plant part of claim 7, further defined as a cell.

11. The plant part of claim 10, wherein said cell is further defined as having :
   (a) an SSR profile in accordance with the profile shown in Table 6; or
   (b) an isozyme typing profile in accordance with the profile shown in Table 7.

12. A seed comprising the cell of claim 10.

13. A tissue culture comprising the cell of claim 10.

14. An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.

17. A tissue culture of regenerable cells of a plant of corn variety I026458, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

18. The tissue culture of claim 17, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

19. The tissue culture of claim 18, wherein the regenerable cells comprise protoplasts or callus cells.

20. A corn plant regenerated from the tissue culture of claim 17, wherein the corn plant is capable of expressing all of the physiological and morphological characteristics of the corn variety designated I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

21. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein one or both of the first or the second parent corn plant is a plant of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228, wherein seed is allowed to form.

22. The process of claim 21, further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein the first or second inbred corn plant is a plant of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

23. The process of claim 22, wherein crossing comprises the steps of:

(a) planting the seeds of first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) preventing self pollination of at least one of the first or second inbred corn plant;

(d) allowing cross-pollination to occur between the first and second inbred corn plants; and

(e) harvesting seeds on at least one of the first or second inbred corn plants, said seeds resulting from said cross-pollination.

24. Hybrid corn seed produced by the process of claim 23.

25. A hybrid corn plant produced by growing a seed produced by the process of claim 23.

26. The hybrid corn plant of claim 25, wherein the plant is a first generation (F_1) hybrid corn plant.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

29. The corn plant of claim 27, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I026458, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I026458 by crossing a plant of the corn variety I026458 with a second corn plant, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I026458.

APPENDIX 3: PENDING CLAIMS WITHOUT ENTRY OF THE AMENDMENT UNDER 37 C.F.R. §1.116

1. A seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

2. A population of seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

4. The population of seed of claim 2, further defined as essentially free from hybrid seed.

5. A corn plant produced by growing a seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

6. The corn plant of claim 5, having:
   (a) an SSR profile in accordance with the profile shown in Table 6; or
   (b) an isozyme typing profile in accordance with the profile shown in Table 7.

7. A plant part of the corn plant of claim 5.

8. The plant part of claim 7, further defined as pollen.

9. The plant part of claim 7, further defined as an ovule.

10. The plant part of claim 7, further defined as a cell.

11. The plant part of claim 10, wherein said cell is further defined as having :
   (a) an SSR profile in accordance with the profile shown in Table 6; or

(b) an isozyme typing profile in accordance with the profile shown in Table 7.

12. A seed comprising the cell of claim 10.

13. A tissue culture comprising the cell of claim 10.

14. An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.

17. A tissue culture of regenerable cells of a plant of corn variety I026458, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

18. The tissue culture of claim 17, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

19. The tissue culture of claim 18, wherein the regenerable cells comprise protoplasts or callus cells.

20. A corn plant regenerated from the tissue culture of claim 17, wherein the corn plant is capable of expressing all of the physiological and morphological characteristics of the corn

variety designated I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

21. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein one or both of the first or the second parent corn plant is a plant of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228, wherein seed is allowed to form.

22. The process of claim 21, further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein the first or second inbred corn plant is a plant of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

23. The process of claim 22, wherein crossing comprises the steps of:

(a) planting the seeds of first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) preventing self pollination of at least one of the first or second inbred corn plant;

(d) allowing cross-pollination to occur between the first and second inbred corn plants; and

(e) harvesting seeds on at least one of the first or second inbred corn plants, said seeds resulting from said cross-pollination.

24. Hybrid corn seed produced by the process of claim 23.

25. A hybrid corn plant produced by growing a seed produced by the process of claim 23.

26. The hybrid corn plant of claim 25, wherein the plant is a first generation (F_1) hybrid corn plant.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

29. The corn plant of claim 27, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I026458, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I026458 by crossing a plant of the corn variety I026458 with a second corn plant, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I026458.

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Main Entry: **pop·u·la·tion**
Pronunciation: "pä-py&-'lA-sh&n
Function: *noun*
Etymology: Late Latin *population-, populatio,* from Latin *populus*
Date: 1612
1 a : the whole number of people or inhabitants in a country or region **b :** the total of individuals occupying an area or making up a whole **c :** the total of particles at a particular energy level -- used especially of atoms in a laser
2 : the act or process of populating
3 a : a body of persons or individuals having a quality or characteristic in common **b** (1) **:** the organisms inhabiting a particular locality (2) **:** a group of interbreeding organisms that represents the level of organization at which speciation begins
4 : a group of individual persons, objects, or items from which samples are taken for statistical measurement
- **pop·u·la·tion·al** /-shn&l, -sh&-n&l/ *adjective*

Pronunciation Symbols

Click on the example word to hear it pronounced.

\&\ as **a** and **u** in abut	\e\ as **e** in bet	\o\ as **aw** in law
\ᵊ\ as **e** in kitten	\E\ as **ea** in easy	\oi\ as **oy** in boy
\&r\as **ur/er** in further	\g\ as **g** in go	\th\ as **th** in thin
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\ch\ as **ch** in chin	\O\ as **o** in go	\zh\ as **si** in vision

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One entry found for **homogeneous**.

Main Entry: **ho·mo·ge·neous**
Pronunciation: `-'jE-nE-&s, -ny&s`
Function: *adjective*
Etymology: Medieval Latin *homogeneus, homogenus,* from Greek *homogenEs,* from *hom-* + *genos* kind -- more at KIN
Date: 1641
1 : of the same or a similar kind or nature
2 : of uniform structure or composition throughout <a culturally *homogeneous* neighborhood>
3 : having the property that if each variable is replaced by a constant times that variable the constant can be factored out : having each term of the same degree if all variables are considered <a *homogeneous* equation>
- **ho·mo·ge·neous·ly** *adverb*
- **ho·mo·ge·neous·ness** *noun*

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One entry found for **accordance**.

Main Entry: **ac·cor·dance**
Pronunciation: `&-'kor-d&n(t)s`
Function: *noun*
Date: 14th century
1 : AGREEMENT, CONFORMITY <in *accordance* with a rule>
2 : the act of granting

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One entry found for **derive**.

Main Entry: **de·rive**
Pronunciation: `di-'rIv, dE-`
Function: *verb*
Inflected Form(s): **de·rived; de·riv·ing**
Etymology: Middle English, from Middle French *deriver,* from Latin *derivare,* literally, to draw off (water), from *de-* + *rivus* stream -- more at RUN
Date: 14th century
transitive senses
1 a : to take, receive, or obtain especially from a specified source
b : to obtain (a chemical substance) actually or theoretically from a parent substance
2 : INFER, DEDUCE
3 *archaic* **:** BRING
4 : to trace the derivation of
intransitive senses **:** to have or take origin **:** come as a derivative
synonym see SPRING
- de·riv·er *noun*

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One entry found for **protoplast**.

Main Entry: **pro·to·plast**
Pronunciation: 'prO-t&-"plast
Function: *noun*
Etymology: Middle French *protoplaste,* from Late Latin *protoplastus* first human, from Greek *prOtoplastos* first formed, from *prOt-* prot- + *plastos* formed, from *plassein* to mold -- more at PLASTER
Date: 1532
1 : one that is formed first **:** PROTOTYPE
2 : a plant cell that has had its cell wall removed; *also* **:** the nucleus, cytoplasm, and plasma membrane of a cell as distinguished from inert walls and inclusions

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For more information see the Guide To Pronunciation.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Francis L. Garing

Serial No.: 09/772,520

Filed: January 29, 2001

For: PLANTS AND SEEDS OF CORN VARIETY I026458

Group Art Unit: 1638

Examiner: Mehta, A.

Atty. Dkt. No.: DEKA:276US

CERTIFICATE OF MAILING
37 C.F.R. §1.8

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SUPPLEMENTAL BRIEF ON APPEAL

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Francis L. Garing	Group Art Unit: 1638
Serial No.: 09/772,520	Examiner: Mehta, A.
Filed: January 29, 2001	Atty. Dkt. No.: DEKA:276US
For: PLANTS AND SEEDS OF CORN VARIETY I026458	

SUPPLEMENTAL BRIEF ON APPEAL

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Sir:

Appellants hereby submit an original and two copies of this Supplemental Appeal Brief. This Brief is filed pursuant to the Request For Reinstatement Of Appeal Under 37 C.F.R. §1.193(B)(2) filed concurrently herewith. The date for filing the instant Brief is December 23, 2003, based on the mailing of the Third Office Action withdrawing the case from appeal on October 23, 2003.

The fee for filing this Supplemental Appeal Brief was filed with the first Appeal Brief mailed on June 30, 2003. No additional fees are believed due in connection with the instant paper. However, should any fees be due, the Commissioner is authorized to withdraw the appropriate fee from Fulbright & Jaworski L.L.P. Deposit Account No. 50-1212/DEKA:276US. Please date stamp and return the enclosed postcard to evidence receipt of this document.

I. REAL PARTIES IN INTEREST

The real party in interest is Monsanto Company, the parent company of wholly-owned subsidiary DeKalb Genetics Corporation, the assignee of this application.

II. RELATED APPEALS AND INTERFERENCES

Appeals were filed in U.S. Patent Application Ser. No. 09/772,520; U.S. Patent Application Ser. No. 09/788,334; U.S. Patent Application Ser. No. 09/606,808; U.S. Patent Application Ser. No. 10/077,589; and U.S. Patent Application Ser. No. 10/077,591, which are also directed to inbred corn plants and contain some of the same rejections as in this case and therefore may have a bearing on the Board's decision in the pending appeal.

III. STATUS OF THE CLAIMS

Claims 1-31 were filed with the application and were pending at the time of the final Office Action. Claims 1, 2, 5-13 and 15-20 were allowed in the final Office Action and claims 3, 4, 14, 21 and 24-31 were rejected. After an Appeal by Applicants and filing of an Appeal Brief, the Examiner re-opened prosecution and removed the rejection of claim 21 under 35 U.S.C. §112, second paragraph, and added rejections of claims 2, 6, 11, 15, 16-20, 22, 28 and 30 for alleged indefiniteness under 35 U.S.C. §112, second paragraph; claims 2, 6 and 11 for an alleged lack of written description under 35 U.S.C. §112, first paragraph and claims 27-30 under 35 U.S.C. §112, first paragraph, for an alleged lack of enablement. The rejections were not necessitated by an amendment to the claims and thus the impetus for adding the rejections at this time is unclear to Appellants.

Claim 4 was cancelled in an Amendment Under 37 C.F.R. §1.116 filed with the Appeal Brief on June 30, 2003. The status of the Amendment was not indicated in the Third Office Action and is currently unknown. The appeal of this claim has been withdrawn. No other claims

have been canceled. Claims 1-31 were thus pending prior to the entry of the 116 Amendment and claims 1-3 and 5-31 pending after entry of the Amendment. Claims 2, 3, 6, 11, 14-22 and 24-31 have been rejected and are the subject of the instant appeal. A copy of the appealed claims is attached hereto as Appendix 1 and a copy of the pending claims after entry of the Amendment under 37 C.F.R. §116 is attached as Appendix 2. A copy of the pending claims without the entry of the Amendment is attached as Appendix 3.

IV. STATUS OF AMENDMENTS

An Amendment Under 37 C.F.R. §1.116 was filed with the Appeal Brief on June 30, 2003. The status of the Amendment was not indicated in the Third Office Action and is currently unknown. No other amendments were made subsequent to the final Office Action. The

V. SUMMARY OF THE INVENTION

The invention relates to the novel inbred corn plant designated I026458 and seeds or populations of seed thereof. Specification at page 5, lines 5-22. The invention also relates to single locus converted plants of I026458. Specification at page 6, lines 12-21. The invention further relates to methods for breeding I026458 with other corn plants, and hybrid plants produced thereby. Specification from page 7, line 23 to page 9, line 16.

VI. ISSUES ON APPEAL

(1) Are claims 2, 3, 6, 11, 14-20, 22, 28 and 30 properly rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out the subject matter which applicants regard as the invention?

(2) Are claims 2, 3, 6, 11, 14, 21 and 24-31 properly rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to convey that the applicants were in possession of the claimed invention?

(3) Are claims 27-30 properly rejected under 35 U.S.C. §112, first paragraph, as lacking enablement?

VII. GROUPING OF THE CLAIMS

Claim 2 is directed to a population of seed of the corn variety I026458, whereas claim 3 is directed to an essentially homogeneous population of seed of corn variety I026458 and claim 14 is directed to an essentially homogeneous population of corn plants produced by growing the seed of corn variety I026458. The analysis of issues on appeal for claims 3 and 14 turns on the meaning of "essentially homogeneous," and thus the claims stand or fall together, but separately from claim 2 and the remaining claims, which are directed to distinct subject matter with different issues on appeal. The analysis of claims 6 and 11 turns on the interpretation of the term "in accordance with" and thus these claims stand or fall together but separately from the remaining claims. The rejection of claims 15, 17 and 20 turns on the interpretation of the term "capable of expressing" and thus these claims stand or fall together but separately from the remaining claims. The rejection of claims 16 and 27 turns on whether the claims broaden the scope of the claims from which they depend and thus these claims stand or fall together but separately from the remaining claims. Claims 18, 19, 22, 28 and 30 have been rejected separately for various allegedly indefinite terms and thus these claims stand or fall separately for these rejections. Independent claim 21 is directed to a process of producing corn seed comprising crossing first and second corn plants, whereas claims 24-26 are directed to hybrid plants produced by certain embodiments of this process. Process and product claims present

different issues for the analysis of written description under 35 U.S.C. §112 and thus claims 21 and 24-26 each stand or fall separately from the remaining claims on appeal, while claims 24-26 stand or fall together. Claims 27-30 are directed to a corn plant of variety I026458 which comprises a single locus conversion and, therefore, these claims stand or fall together. Claims 27-30 stand or fall separately from the remaining appealed claims, as the rejection of only these claims centers on whether written description has been provided for a single locus conversion of corn plant I026458, and the issue is distinct from other issues on appeal. Another appealed independent process claim is present in the case in addition to claim 21, claim 31, but comprises a distinct series of steps from claim 21, and thus presents different written description issues on appeal. The claim therefore stands or falls separately from both claim 21 and the remaining claims.

VIII. SUMMARY OF THE ARGUMENT

The Examiner has made 11 separate indefiniteness rejections. The rejections have been made without consideration of the repeated caution by the Federal Circuit that all that is necessary under the second paragraph of §112 is that one of skill in the art understand the metes and bounds of what is being claimed. As set forth individually below, the metes and bounds of the properly construed claims are clear to one of skill in the art.

The written description rejections fail because the claimed subject matter has been fully described. Each of the claimed hybrid plants and seeds having inbred corn plant I026458 as one parent have as half of their genome the same genetic contribution from I026458, given that corn plant I026458 is inbred. This structural characteristic is readily detectable and thus defines the claimed plants. These plants can be produced using any second plant, thus written description with regard to the second parent is satisfied based on the countless corn varieties known to those

of skill in the art, including the more than 300 corn varieties for which utility patents have previously been issued. Methods of crossing the claimed corn variety have been fully described in the recited steps, and such corn breeding steps were well known in the art. Single locus conversions of I026458 were also fully described, in that well more than a representative collection of single locus conversion traits are described in the specification and were well known to those of skill in the art. The single locus conversion traits themselves are further not being claimed, rather it is corn plant I026458 comprising any given single locus conversion that is claimed.

The enablement rejections fail because Appellants working examples and descriptions in the specification fully enable the claimed subject matter. The Examiner has improperly disregarded this evidence and failed to support the rejections in contradiction of the standards of the APA.

IX. ARGUMENT

A. The Rejections Under 35 U.S.C. §112, Second Paragraph, Are Improper

1. Rejection of claim 3

The Examiner rejected claims 3 and 4 as allegedly broadening the claims from which they depend. Claim 4 has been canceled and thus the rejection is now moot. With respect to claim 3, it is noted that the claim does not broaden the scope of the claim from which it depends, claim 2. Claim 2 reads as follows:

> 2. A population of seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

Claim 3 specifies the population of seed of claim 2, "further defined as an essentially homogeneous population of seed." Claim 3 thus further defines the population of claim 2 as

being "essentially homogeneous." While claim 2 is directed to a population of seed of the corn variety I026458, it is not necessary that the population be an essentially homogeneous population of seed. A population may not be essentially homogeneous yet still be a population. For example, the relevant definition of "population" from the on-line version of the Merriam-Webster™ dictionary is "a body of persons or individuals having a quality or characteristic in common." **Exhibit A**. In contrast, the definition for "homogeneous" from the same on-line dictionary is given as "of uniform structure or composition throughout." **Exhibit B**. Therefore a collection of seed may at one time have a quality or characteristic in common, *e.g.*, be of variety I026458, yet not be of uniform structure or composition throughout. For example, a population of seed of corn variety I026458 could be non-uniform in size or shape, due to growth or other conditions, yet still have the common quality of being a corn plant of variety I026458. As such, claim 3 is in proper dependent form and is not indefinite. Reversal of the rejection is thus respectfully requested.

2. Rejection of claim 14

The Examiner has also maintained the rejection of claim 14 as being indefinite for reciting the term "essentially homogeneous population." Claim 14 reads as follows:

> 14. An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

Appellants again note that, as set forth above, a population need not be essentially homogeneous, whether a population of plants or seeds. Further defining a population as essentially homogeneous does not render the claim indefinite. A population of plants grown from the seed of corn variety I026458 could vary in size or other characteristics due to environmental or other conditions, but still constitute a population of corn plant produced by growing the seed of corn variety I026458. As such, "essentially homogeneous" further defines

the scope of the claim and the term as it is used is not indefinite. Reversal of the rejection is thus respectfully requested.

3. Rejection of claim 2

The Examiner rejects claim 2 taking the position that "population of seed of the corn variety I026458" is unclear on the basis that an express definition is not provided for "population" and based on a citation the Examiner makes to a particular use of the term in the specification. In response, Appellants note that the term "population" has a well known meaning in the art and thus the use of the term in the claims is not indefinite. Claim terms are given their plain meaning and limitations from the specification are not read into a claim. Provided herewith as evidence of the well known meaning of "population" is a copy of the definition for this term from the on-line version of the Merriam-Webster™ dictionary. **Exhibit A**. The term is therefore fully definite and removal of the rejection is respectfully requested.

4. Rejection of claims 6 and 11

The Action states that "in accordance with" renders the claim indefinite because the meaning of the term is not exactly clear. In response, Appellants note that the term has a well known meaning in the art. As evidence of the meaning, Appellants have attached hereto the dictionary definition for "accordance" from the on-line version of the Merriam-Webster™ dictionary. (**Exhibit C**). As can be seen, the definition given is "agreement, conformity." The example sentence given in the definition is "in accordance with a rule" The Examiner has provided no basis to conclude why the claim would be indefinite in view of this well known meaning. The use of the term in the claim is thus not indefinite and removal of the rejection is respectfully requested.

5. Rejection of claims 15, 17 and 20

The Examiner rejects claims 15, 17 and 20 for use of the term "capable of expressing." In particular, it is stated that it is unclear if the plant actually expresses the trait. Appellants note that the term "capable" is well know in the art and thus the claim is fully definite. Claim breadth is not indefiniteness. One of skill in the art would understand whether a corn plant is capable of expressing all of the traits of corn plant I026458 because Appellants have provided the corn plant I026458 by way of a biological deposit with the ATCC. One of skill in the art would therefore readily ascertain whether a plant is capable of expressing all of the traits of I026458 based on direct comparisons. Because the standard is readily ascertainable, the use of the limitation in the claims is not indefinite. Reversal of the rejection is therefore respectfully requested.

6. Rejection of claims 16 and 27

The Action rejects the claims as allegedly broadening the scope of the claims from which they depend. It is in particular stated that the claims "add on a gene or locus to the genome of the plant of their parent claims" and that there is no indication how the plants acquired the gene and that the gene is not possessed by the plant of the parent claims.

Appellants do not understand the rejection. As stated in the sentences explaining the rejection, the claims further narrow the claim from which they depend because the claims specify a further limitation ("add on a gene"), and the limitation is not possessed by the parent claims. Specifically, claims 16 adds "a nuclear or cytoplasmically-inherited gene conferring male sterility," while claim 27 adds "a single locus conversion," neither element of which is required by the main claim. Therefore, both claims (1) ***contain a reference to parent claim*** from which they depend, (2) contain a ***further limitation*** of the subject matter claimed in the main claim, and (3) ***incorporate all elements*** of the claim from which they depend. The claims are therefore in proper dependent form pursuant to 37 C.F.R. §1.75(c) and are fully definite. As to how the

plants acquire the added elements, this is irrelevant to the scope or definiteness of the claims, as the claims are product claims, not process or product by process claims. Reversal of the rejection is therefore respectfully requested.

7. Rejection of claim 18

The Action rejects claim 18 taking the position that "derived from" in the recitation "wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks" is indefinite.

Appellant note that the term is fully definite based on the well known meaning of "derived." For example, the relevant dictionary definitions for "derived" from the on-line version of the Merriam-Webster™ dictionary are "**1 a :** to take, receive, or obtain especially from a specified source **b :** to obtain (a chemical substance) actually or theoretically from a parent substance." **Exhibit D**. Both definitions indicate that in this case the regenerable cells are obtained from the relevant compositions. Given the well known meaning, there is nothing indefinite in the recitation of the term in the claims. Reversal of the rejection is therefore respectfully requested.

8. Rejection of claim 19

The Action rejects claim 19 for use of the term "the regenerable cells comprise protoplasts" because it is stated that protoplasts are not cells. However, Appellants note that the relevant dictionary definition from the on-line version of the Merriam-Webster™ dictionary for "protoplast" is "a plant cell that has had its cell wall removed." **Exhibit E**. A cell may therefore be a protoplast, although its cell wall has been removed. In view of this, the recitation of "cells

are in the form of protoplasts" is not indefinite. Reversal of the rejection is therefore respectfully requested.

9. Rejection of claim 22

The Action rejects claim 22 as allegedly being improperly dependent on claim 21 for not further limiting this claim. This is incorrect. Claim 22 specifies that corn plant I026458 is crossed to a second, distinct inbred corn plant, whereas claim 21 is not so limited. In claim 21, I026458 may be crossed to a second plant that is not distinct from I026458 and is not inbred. In claim 22, I026458 must be crossed to a second, distinct inbred corn plant. Claim 22 therefore further narrows claim 21 and is in proper dependent form. The rejection of the Examiner is thus not understood. Reversal of the rejection is therefore respectfully requested.

10. Rejection of claim 28

The Action states that claim 28 is indefinite because the article "a" in the recitation "wherein the single locus was stably inserted into a corn genome" renders the claim indefinite regarding whether the single locus was inserted into the genome of I026458 or that of a different plant.

The single locus referred to in claim 28 may or may not have been directly inserted into the genome of the claimed plant. This does not render the claim indefinite, however. The single locus may have been inserted into a parent I026458 plant selfed to produce the claimed plant. The claim specifies that the single locus was stably inserted into a corn genome. Loci that are stably inserted into a corn genome are also stably inherited. Thus the single locus need not have been inserted into the genome of corn variety I026458. As such, the metes and bounds of the claim are clear and the claim is not indefinite. Reversal of the rejection is therefore respectfully requested.

11. Rejection of claim 30

The Action rejects claim 30 for use of the terms "yield enhancement," "improved nutritional quality," and "enhanced yield stability." However, the terms are all understood by those of skill in the art and there is no prohibition upon the use of relative terms. The terms must be read in the context of the claim in which they are found. The subject claim recites a single locus that confers the traits of yield enhancement, improved nutritional quality, and enhanced yield stability. It is thus understood the enhancement of yield or yield stability and improved nutritional quality is relative to a plant lacking the single locus. The metes and bounds of the claim are thus fully understood by one of skill in the art and the use of the terms is not indefinite. Reversal of the rejection is therefore respectfully requested.

B. The Written Description Rejection of Claims 2, 3, 6, 11, 14, 21 and 24-31 Is Improper

1. Populations of seed and plants grown therefrom recited in claims 2, 3 and 14 have been fully described

The Action rejects claims 2 and 3 as allegedly not having been adequately described.

Claim 2 reads as follows:

> 2. A population of seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3224.

Claim 3 reads as follows:

> 3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

Claim 2 finds literal support in the deposit of seed made with the ATCC and thus the rejection is not understood. Specifically, Appellants have deposited a population of 2500 seeds with the ATCC, fully supporting the claim. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d

1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). With regard to claim 3, as set forth above, this is a proper dependent claim that further defines claim 2. This is because a population, which is a group of individuals sharing a common characteristic, need not be substantially homogeneous. This also has literal support in the recited seed deposit as claim 2, as an essentially homogeneous population may be prepared, for example, by selecting seeds from the population of claim 2 having shared selected characteristics, for example, seed weight, seed size or seed shape. Claim 14, directed to an essentially homogeneous population of corn plants produced by growing the seed of the corn variety I026458, has similarly been described. As indicated above, "essentially homogeneous" properly modifies "population." The Examiner has not alleged that populations of corn plants produced by growing the seed of the corn variety I026458 have not been described. Reversal of the rejections is thus respectfully requested.

2. The marker profiles in claims 6 and 11 have been described

The Action rejects claims 6 and 11 because it is stated that written description for the markers named in Tables 6 and 7 has not been provided. Initially, it is noted that no basis for this allegation has been provided. The profiles are recited in the tables and the claims claim nothing more than what is provided in Tables 6 and 7. Literal support is therefore found in the specification.

With regard to the markers themselves, the SSR markers were from Celera AgGen, Inc., which provides a commercial service for genotyping of maize varieties. Nothing is therefore indefinite about the recitation of the marker phenotypes. With regard to the isozymes, the markers are well known and isozyme analysis in general very well known having been used for decades. The claimed subject matter has therefore been fully described.

3. Hybrid plants recited in claims 22-24 have been fully described

a. The claimed hybrid plants share the genetic complement of corn variety I026458

Rejected claims 22-24 are directed to hybrid plants and seeds produced with corn plant I026458 as one parent. Appellants have fully described this claimed subject matter in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. As set forth in the breeding history at pages 26-27 of the specification, corn plant I026458 is an inbred corn plant. All of the claimed hybrid plants having I026458 as a parent will therefore contain a copy of the same genome as corn plant I026458. That is, because I026458 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant I026458, save the possibility of the rare spontaneous mutation or undetected segregating locus. This entire genetic contribution of corn plant I026458 is described in the specification by way of the deposit of seed of corn plant I026458 with the ATCC. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). This represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants in full compliance with the written description requirement.

The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus,*

visualize or recognize the identity of the members of the genus" (emphasis added)). Here, all of the members of the claimed genus of hybrids having I026458 as one parent share the structural feature of having the genetic complement of I026458. One of skill in the art could thus readily identify the members of the genus. The written description requirement has, therefore, been fully complied with.

b. The entire genetic complement of variety I026458 is described by way of the proffered deposit of seed

Appellants describe the entire genetic sequence of corn variety I026458 by way of the biological deposit of seed with the ATCC. In particular, the Federal Circuit has recently held that a biological deposit may be used to satisfy written description for nucleic acids, whether the nucleic acid sequence is set forth in the specification or not. In *Enzo Biochem, Inc. v. Gen-Probe Inc.*, the patent owner had deposited six strains of *N. gonorrhoeae* and claimed nucleotide sequences hybridizing to the nucleic acids of these strains, but the patent application did not set forth the nucleic acid sequences of these strains in the specification. 296 F.3d 1316, 1328 (Fed. Cir. 2002). The Federal Circuit nonetheless held that "as those bacteria were deposited, their ***bacterial genome is accessible*** and, under our holding today, they are ***adequately described in the specification by their accession numbers***." (emphasis added) *Id.* In its holding, the Federal Circuit considered the burden that would be placed on applicants were they required to sequence each of the strains, noting lower court findings that it would have taken 3,000 scientists a month to sequence the bacterial genome of one strain of *N. gonorrhoeae*. *Id.* In the instant case, even more effort would be required, as corn is a higher life form with a more complex genome than the bacteria deposited in *Enzo*. The Examiner would nonetheless appear to require this much of Appellants in direct contradiction of *Enzo*.

c. The Examiner Incorrectly States the Holding of *Enzo*

The Examiner attempted to counter the showing by Appellants that the holding of *Enzo* establishes a written description for the genome of corn variety I026458 by stating that *Enzo* is inapplicable because in that case a function was correlated with the deposited product. However, this constitutes a misstatement of the holding of *Enzo* that obfuscates the legal principle for which the case stands. First, the alleged "function" in *Enzo* was the ability to hybridize to the deposited sequences. *Enzo*, 296 F.3d at 1323. This is in reality no function at all, but rather is a structural limitation, given that only sequences with a given degree of homology will hybridize. Second, the question in *Enzo* was not whether a function had to be disclosed in order to have adequate written description for a claimed sequence, rather it was whether a sequence could be claimed by way of a function when it was described in the specification only by way of a deposit. This is illustrated by the statement of issues presented made by the Federal Circuit:

> we first inquire whether Enzo's deposits of the claimed nucleotide sequences of claims 4 and 6 may constitute an adequate description of those sequences. Secondly, we will consider whether the description requirement is met for all of the claims on the basis of the functional ability of the claimed nucleotide sequences to hybridize to strains of *N. gonorrhoeae* that are accessible by deposit.
>
> *Id.* at 1325.

These are distinct issues. To the first question, the Federal Circuit expressly stated that a deposit constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, P 1. Specifically the court stated"[w]e therefore agree with Enzo that reference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement." *Id.* at 1326. The Federal Circuit did not make or condition this holding on a function that was disclosed. The question was whether the deposit satisfied written description for the claimed nucleic acid sequences, which the court held that it did. There is, therefore, no

basis to conclude that the holding in *Enzo* does not demonstrate that Appellants have provided a written description of the entire genetic complement of corn variety I026458 based on the deposit with the ATCC.

d. The shared characteristics of the claimed hybrid plants are readily identified and described in the specification

As set forth above, the claimed F1 hybrid plants having I026458 as one parent will share the same genetic complement received from I026458. This is readily identifiable by genetic marker analysis, as shown in Tables 6 and 8 of the specification. There shown is the SSR genetic marker profile of corn variety I026458, as well as an the exemplary hybrid plant designated 7041221 that was made using I026458 as one parent. As can be seen, hybrid corn plant 7041221 has the SSR genetic marker profile of I026458, and also includes the genetic markers from the second parent plant used to make the hybrid. The same will be true for any other hybrid plant having I026458 as one parent, save for an occasional difference at a locus due to spontaneous genetic rearrangements, which occur at statistically insignificant frequencies in essentially all organisms.

The second plant that is used to make the claimed hybrid plants is irrelevant, as a hybrid will be produced any time corn plant I026458 is crossed with a second plant. That is, any second plant capable of reproduction may be used to make the hybrid plant. Appellants cannot therefore be said to lack written description for the second genetic complement. This is particularly so given that hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing of the instant application, each of which could be crossed to make a hybrid plant within the scope of the claims. This is evidenced by a review of the U.S.P.T.O. patent data website, which reveals utility patents issued on hundreds of different corn varieties. Any one of these corn plants, or the many hundreds or thousands of other maize plants

that were known at the time the application was filed, could be used to produce an F1 hybrid plant having corn variety I026458 as one parent, and each of these would share the genetic complement of I026458.

Written description is reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The specification need not disclose what is well-known to those skilled in the art and preferably omits what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). As ***any*** different second plant may be used to produce the claimed hybrid plants and such plants were well known to those of skill in the art, Appellants cannot be said to have not been in possession of the second parent plant. The claimed hybrid corn plants have therefore been described in compliance with 35 U.S.C. §112, first paragraph.

The Action attempts to downplay the significance of the genetic marker data given in the specification by stating that some loci may be shared by other plants, that primer sequences are not described or that certain isozyme markers are not informative. However, no effort has been made to show that any substantial number of marker loci actually *are* shared by other plants. Further, Appellants do not claim such "other" plants, so this is irrelevant to written description. No basis has been provided to conclude that the claimed hybrid plants are not distinct and clearly identifiable by the genetic marker profile that has been set forth. Regarding the availability of genetic markers, the service that was used to detect SSR markers is commercially available to the public. Further, SSR and any of the other genetic marker systems that are well known to those of skill in the art may potentially be used, as is described on pages 60-61 of the specification. Regardless of whether SSR markers are used, the shared genetic complement of the claimed hybrid plants having corn variety I026458 as one parent distinguishes them. As the entire

genome of corn variety I026458 has been described, at least, by way of the seed deposit that has been made, any polymorphic locus could be used including or in addition to the SSR markers shown in Tables 6 and 8.

e. The Examiner's allegations that the expression of the genetic complement of corn variety I026458 is unpredictable are inapposite

The Examiner alleges that claimed hybrid plants have not been described despite inheriting the genetic complement of variety I026458 because information is not provided regarding the morphological and physiological traits of the hybrid plants. It is alleged that how the genes that are inherited would be expressed or would interact has not been shown. However, this misses the point that Appellants have gone one step further than morphological and physiological traits by describing the claimed hybrid plants at the genetic level. A better description could not be made than at the genetic level. Morphological and physiological traits, while helpful, are also subject to environmental variation and require subjective gradations. Genetic testing goes to the source of traits and yields concrete values.

The law further makes no distinctions regarding the manner in which Appellants choose to describe claimed compositions. Rather, an applicant must merely describe the claimed subject matter by "whatever characteristics sufficiently distinguish it." *Amgen v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Here, Appellants have described the genetic complement of parent plant I026458 that will be comprised in the claimed hybrid plants. This has been achieved using the SSR and isozyme genetic marker profiles given in tables 6-9 of the specification. Indeed, Appellants describe the entire genetic complement of parent plant I026458 by way of a seed deposit made with the ATCC. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002).

f. Appellants fully describe an exemplary hybrid made using inbred I026458

Further description of claimed hybrid plants is also provided in the specification by way of a detailed description of hybrid 7041221, which was produced with I026458 as one inbred parent. This plant is representative of hybrids produced using I026458 as one parent, each of which comprise the genetic complement of the parent corn plant as set forth above. Table 4 of the specification gives the performance characteristics for 7041221 and provides comparisons against other hybrid varieties. In Table 5, the morphological traits of 7041221 are given. The SSR and isozyme marker profiles for hybrid 7041221 are given in Tables 8 and 9, respectively. This information, combined with the descriptions of I026458 in the specification and the shared structure among hybrids having corn plant I026458 as a parent, is more than adequate to describe the claimed subject matter.

4. Single locus converted plants of corn variety I026458 have been fully described

The Examiner has maintained the rejection of claims 27-30, which are directed to a single locus conversion of corn plant I026458. In particular, the Examiner has alleged that: (1) the characteristics of the claimed single locus converted plant are unpredictable and/or not described, (2) the claims encompass genes that have yet to be discovered, and (3) the sequences and/or sources for the numerous examples of single locus traits disclosed in the application have not been described.

a. The claimed subject matter is not unpredictable

With regard to the first point made by the Examiner, it is noted that a "single locus converted (conversion) plant" is defined at page 23, lines 6-12 of the specification as follows:

> [p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics

> conferred by the single locus transferred into the inbred *via* the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Therefore, the claimed plants comprising a single locus conversion possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]". The Examiner's comments with regard to various allegedly unknown characteristics are thus outside the scope of the claims. With regard to the claimed subject matter, Appellants have more than adequately described such a plant that comprises essentially all of the desired morphological and physiological characteristics of corn plant I026458 by way of the description and deposit of I026458 alone, not to mention other description provided. To hold otherwise would be to limit Appellants to that subject matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)) .

b. The Examiner has applied the written description requirement with respect to unclaimed subject matter

With respect to the Examiner's allegation that the claims encompass genes that have yet to be discovered, it is noted that Appellants ***do not claim undiscovered genes***. The claimed subject matter is the corn variety I026458 comprising a single locus conversion. Any single locus conversion may be introduced into corn variety I026458 to produce the claimed single locus conversion. The fact that a given gene could be isolated in the future and introduced as a single locus conversion is irrelevant – the new gene is not claimed *per se*, a single locus conversion of corn plant I026458 is claimed. Under the reasoning of the Examiner, essentially

any claim could be read to encompass subject matter yet to be invented and therefore not be described. A claim to a corn plant transformed with a *Bacillus thuringiensis* gene would be invalid because it would encompass corn varieties yet to be discovered. A claim to a given gene operably linked to a regulatory element would be invalid because as yet to be isolated regulatory elements would be encompassed. Nearly any biotechnological invention could be viewed this way applying the Examiner's reasoning. However, it is not any given single locus that is claimed, it is a corn plant of corn variety I026458 which comprises a single locus that has been claimed.

c. Appellants have disclosed numerous single locus traits and such traits were well known to those of skill in the art when the application was filed

The Examiner alleges that the traits recited in the application and referred to in Appellants previous response to office action have not been shown to have been known in the art. The Examiner has therefore invited Appellants to amend the claims to recite individual examples of single locus traits provided the prior art teaches that those types of genes have been isolated and therefore reduced to practice. However, the Examiner has ignored Appellants previous evidence submitted in the prior response to office action and also recited in the specification showing numerous single locus traits that were described.

Among just the examples in the specification recited with a publication reference or patent number are the following (see specification at pages 30-35): genes conferring male sterility (U.S. Patent No. 3,861,709, U.S. Patent No. 3,710,511, U.S. Patent No. 4,654,465, U.S. Patent No 5,625,132, and U.S. Patent No. 4,727,219, incorporated by reference); male-sterility restorer genes (U.S. Patent Nos. 5,530,191, 5,689,041, 5,741,684, and 5,684,242, incorporated by reference); a herbicide resistant EPSPS mutation termed *aroA* (U.S. Patent 4,535,060); and a

mutant maize gene encoding a protein with amino acid changes at residues 102 and 106 (PCT Publication WO 97/04103).

The single locus traits are also described by way of PCT Application Publ. WO 95/06128, which was specifically incorporated by reference at page 31 of the specification. Examples of some of the single locus traits described in WO 95/06128, including any associated phenotype and publication reference given, are as follows:

the uidA gene from *E. Coli* encoding β-glucuronidase (GUS) (cells expressing *uidA* produce a blue color when given the appropriate substrate, Jefferson, R.A. 1987. *Plant Mol. Biol. Rep* 5: 387-405); the *bar* gene from *Streptomyces hygroscopicus* encoding phosphinothricin acetyltransferase (PAT) (cells expressing PAT are resistant to the herbicide Basta, White, J., Chang, S.-Y.P., Bibb, M.J., and Bibb, M.J. 1990. *Nucl. Ac. Research* 18: 1062); the *lux* gene from firefly encoding luciferase (cells expressing *lux* emit light under appropriate assay conditions, deWet, J.R., Wood, K.V., DeLuca, M., Helinski, D.R., Subramani, S. 1987. *Mol. Cell. Biol.* 7: 725-737); the *dhfr* gene from mouse encoding dihydrofolate reductase (DHFR) (cells expressing *dhfr* are resistant to methotrexate; Eichholtz, D.A., Rogers, S.G., Horsch, R.B., Klee, H.J., Hayford, M., Hoffman, N.L., Bradford, S.B., Fink, C., Flick, J., O'Connell, K.M., Frayley, R.T. 1987. *Somatic Cell Mol. Genet.* 13: 67-76); the *neo* gene from *E.Coli* encoding aminoglycoside phosphotransferase (APH) (cells expressing *neo* are resistant to the aminoglycoside antibiotics; Beck, E., Ludwig, G., Auerswald, E.A., Reiss, B., Schaller, H. 1982. *Gene* 19: 327-336); the *amp* gene from *E. Coli* encoding β-lactamase (cells expressing β-lactamase produce a chromogenic compound when given the appropriate substrate; Sutcliffe, J.G. 1978. *Proc. Nat. Acad. Sci.* USA 75: 3737-3741); the *xylE* gene from *Ps. putida* encoding catechol dihydroxygenase (cells expressing *xylE* produce a chromogenic compound when given the appropriate substrate; Zukowsky *et al.* 1983. *Proc. Nat. Acad. Sci.* USA 80: 1101-1105); the R,C1 and B genes from maize encode proteins that regulate anthocyanin biosynthesis in maize (Goff, S., Klein, T., Ruth, B., Fromm, M., Cone, K., Radicella, J., Chandler, V. 1990. *EMBO J.:* 2517-2522); the ALS gene from *Zea mays* encoding acetolactate synthase and mutated to confer resistance to sulfonylurea herbicides (cells expressing ALS are resistant to the herbicide; Gleen. Yang, L.Y., Gross, P.R., Chen, C.H., Lissis, M. 1992. *Plant Molecular Biology* 18: 1185-1187); the proteinase inhibitor II gene from potato and tomato (plants expressing the proteinase inhibitor II gene show increased resistance to insects; potato - Graham, J.S., Hall, G., Pearce, G., Ryan, C.A. 1986 *Mol. Cell. Biol.* 2: 1044-1051; tomato - Pearce, G., Strydom, D., Johnson, S., Ryan, C.A. 1991. *Science* 253: 895-898); the *Bt* gene from *Bacillus thuringensis* berliner 1715 encoding a protein that is toxic to insects (this gene is the coding sequence of *Bt* 884 modified in two regions for improved expression in plants; Vaeck, M., Reynaerts, A., Hofte, H., Jansens, S., DeBeuckeleer, M., Dean, C., Aeabeau, M., Van Montagu, M., and Leemans, J. 1987. *Nature* 328: 33-37); the *bxn* gene from *Klebsiella ozaeneae* encoding a nitrilase enzyme specific for the herbicide bromoxynil (cells expressing this gene are resistant to the herbicide bromoxynil; Stalker, D.m., McBride, K.E., and Malyj, L. *Science* 242: 419-422, 1988); the WGA-A gene encoding wheat germ agglutinin (expression of the WGA-A

gene confers resistance to insects; Smith, J.J., Raikhel, N.V. 1989. *Plant Mol. Biology* 13: 601-603); the *dapA* gene from *E. coli* encoding dihydrodipicolinate synthase (expression of this gene in plant cells produces increased levels of free lysine; Richaud, F., Richaud, C., Rafet, P. and Patte, J.C. 1986. *J. Bacteriol.* 166: 297-300); the *Z10* gene encoding a 10kd zein storage protein from maize (expression of this gene in cells alters the quantities of 10kD Zein in the cells; Kirihara, J.A., Hunsperger, J.P., Mahoney, W.C., and Messing, J. 1988. *Mol. Gen. Genet.* 211: 477-484); the Bt gene cloned from *Bacillus thuringensis* Kurstaki encoding a protein that is toxic to insects (the gene is the coding sequence of the cry IA(c) gene modified for improved expression in plants - plants expressing this gene are resistant to insects; Höfte, H. and Whiteley, H.R., 1989. *Microbiological Reviews.* 53: 242-255); the ALS gene from *Arabidopsis thaliana* encoding a sulfonylurea herbicide resistant acetolactate synthase enzyme (cells expressing this gene are resistant to the herbicide Gleen. Haughn, G.W., Smith, J., Mazur, B., and Somerville, C. 1988. *Mol. Gen. Genet.* 211: 266-271); the *dehl* gene from *Pseudomonas putida* encoding a dehalogenase enzyme (cells expressing this gene are resistant to the herbicide Dalapon; Buchanan-Wollaston, V., Snape, A., and Cannon, F. 1992. *Plant Cell Reports* 11: 627-631); the hygromycin phosphotransferase II gene from *E. coli* (expression of this gene in cells produces resistance to the antibiotic hygromycin. Waldron, C., Murphy, E.B., Roberts, J.L., Gustafson, G.D., Armour, S.L., and Malcolm, S.K. *Plant Molecular Biology* 5: 103-108, 1985); the *mtlD* gene cloned from *E. coli* (the gene encodes the enzyme mannitol-1-phosphate dehydrogenase; Lee and Saier, 1983. *J. of Bacteriol.* 153:685); the HVA-1 gene encoding a Late Embryogenesis Abundant (LEA) protein (the gene was isolated from barley; Dure, L., Crouch, M., Harada, J., Ho, T.-H. D. Mundy, J., Quatrano, R, Thomas, T, and Sung, R., *Plant Molecular Biology* 12: 475-486.

The foregoing represent just some of the single locus coding sequences that were known as of March 2, 1995; ***nearly six years prior*** to the filing of the instant application. More than 25 regulatory elements were also described therein, as were numerous transformation vectors comprising combinations of these elements. Appellants could describe many more examples of single locus traits that were well known as of the filing date, and would be glad to do so should the Board find it useful. It thus goes without saying that single locus traits were more than well known to those of skill in the art as of the filing date and were fully described in the specification.

Techniques for the introduction of single locus traits by genetic transformation were further well known to those of skill in the art. Some of the transformation methods for corn that were well known as of the filing date and cited in the specification include the following: electroporation (U.S. Patent No. 5,384,253), microprojectile bombardment (U.S. Patent No.

5,550,318; U.S. Patent No. 5,736,369, U.S. Patent No. 5,538,880; and PCT Publication WO 95/06128), *Agrobacterium*-mediated transformation (U.S. Patent No. 5,591,616 and E.P. Publication EP672752), direct DNA uptake transformation of protoplasts (Omirulleh *et al.*, 1993) and silicon carbide fiber-mediated transformation (U.S. Patent No. 5,302,532 and U.S. Patent No. 5,464,765). Introduction of such traits by conventional breeding was also known. In fact, this is one of the most fundamental procedures in agricultural science, and it has not been alleged that this has not been described.

Appellants have therefore shown possession of the claimed single locus conversions. Both large numbers of single locus traits and the associated phenotypes were well known to those of skill in the art. The specification itself defines a single locus converted plant as comprising essentially all of the desired morphological and physiological characteristics of the starting non-converted plant, *e.g.*, I026458. Well more than an adequate number of examples have been provided and were known in the art to satisfy written description. The state of the art must be considered in the written description determination. As such, Appellants respectfully request reversal of the rejection.

5. The rejection of claim 31 has been improperly issued and maintained

a. The Examiner has failed to adequately support the rejections

Claim 31 is a process claim that involve crossing corn variety I026458 according to the specified steps. It is believed that the position of the Examiner is that written description must be provided for each intermediate product in a method claim in the same manner as if the particular product was individually claimed as a composition of matter. That is, Appellants understand that the position taken is that it is not sufficient to describe all of the starting materials for a process and all of the steps carried out on the starting materials, but rather that the structural characteristics of any product made at any intermediate or penultimate step must be described as

if claimed as a composition of matter. Appellants submit that this is a misstatement of the law and, more significantly, note that this rejection has not been adequately set forth on the record. No reasonable basis in law or fact has been given for maintaining the rejection, as the Examiner's arguments appear to be entirely directed to composition of matter claims.

The Examiner cites for "authority" supporting the novel legal position taken in the rejection of claim 31 the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. Sec. 112, ¶'Written Description' Requirement; Request for Comments, 64 Fed. Reg. 71427, 71428 (1999), comment no. 4. Written Description Guidelines, Fed. Reg. Vol. 64, pp 71427, 71428 (1999), comment 4. Third Office Action at p.17, second full paragraph. Specifically, it is stated that "application of the written description guidelines to methods have been adapted." However, the Examiner misconstrues this section. The cited portion states the following:

> (4) Comment: Six comments were in favor of including process and product-by-process claims in the analysis, whereas one comment was opposed. One comment criticized the Guidelines for failing to acknowledge the ``safe harbor" product-by-process type claim noted in Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993), and Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). One comment observed that process and product-by- process claims tend not to implicate many written description issues, and it may be useful to point out possible enablement deficiencies for such claims. Two comments suggested that the Guidelines should distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those where patentability rests in the steps of the process itself. Response: The suggestion to address process and product-by-process claims has been adopted. Furthermore, the training materials will analyze claims wherein the patentability depends on the compositions used therein, as well as those where the patentability rests in the process steps themselves. Enablement issues raised by process and product-by-process claims are outside the scope of these Revised Interim Guidelines.

Appellants find no support in this comment for the position taken. All that the note says is that the Written description Guidelines ***will address*** process and product-by-process claims, *e.g.*, this will be done some time in the future. Indeed the comment appears to indicate that composition

and methods claims will be treated differently, as immediately prior to the sentence indicating that the suggestion will be adopted it is stated that a request was made to "distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those where patentability rests in the steps of the process itself."

Quite tellingly, the Examiner has failed to cite the actual Guidelines themselves in which the issue reserved in the passage of the Interim Guidelines was apparently to be addressed. Appellants direct the Board to the Written Description Guidelines, Fed. Reg. Vol. 66, pp1099-1111 (Jan. 5, 2001). The analysis of written description set forth under these Guidelines involves "(i) Determin[ing] whether the application as filed describes the complete structure (***or acts of a process***) of the claimed invention as a whole." Fed. Reg. Vol. 66, pp1106 (emphasis added). In the next step of the process, the Guidelines state that: "ii) If the application as filed does not disclose the complete structure (***or acts of a process***) of the claimed invention as a whole, determine whether the specification discloses other relevant identifying characteristics sufficient to describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicant was in possession of the ***claimed invention***." *Id.* (emphasis added). These sections clearly demonstrate that the Guidelines distinguish product and process claims. This also illustrates that the Examiner has failed to apply the Guidelines by not considering written description with regard to the claimed invention.

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko,* 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside*, 203 F.3d

1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. As set forth above, the current rejections are unsupported in fact or law. The standards of the APA have therefore not been met and reversal of the rejection is thus respectfully requested.

b. The rejection of claim 31 is contrary to Federal Circuit precedent

As set forth above, it is believed that the rejection is made based on the position that each product produced at any intermediate or penultimate step of the method must be described as if claimed *per se*. However, what is required to meet the written description requirement is that an Applicant show that he or she was in possession of the ***claimed invention***. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Here, a process is claimed, not a product of a process, and thus the steps of that process must be described, not intermediate or final products of the steps. The starting materials for the process must also be provided, otherwise the process could not be completed. However, the only starting materials required are corn variety I026458, which the Examiner does not allege to have not been described, and ***any*** second corn plant. As set forth above, corn plants were well known, and this has also therefore been fully described.

With respect to the steps, these have been fully set forth in the claim. It has not been alleged that any essential steps are absent. All that is required to complete the claimed method is to cross the corn variety I026458 or a product that is produced by any preceding step according to the steps given. All of the starting products for any step within the method are either (1) corn variety I026458, (2) any second corn plant, or (3) a corn plant that is produced by following a preceding method step. The method has therefore been fully described.

It is also noted that corn breeding is well known to those of skill in the art. Without it, there would not be commercial corn varieties, which are typically sold as hybrids produced by crossing two inbred varieties. This is evidenced by the more than 300 issued patents to inbred maize varieties discussed above, given that inbred plants are not produced without multiple generations of intentional self-fertilization. All of the steps recited in claim 31 are typical of the process used for the production of new corn varieties, save for the point of novelty, corn variety I026458. This is evidenced in the breeding history for the production of corn variety I026458, which is given in the specification. The specification also describes methods and considerations for producing new corn varieties in the review of related art, for example, at pages 2-4 of the application.

In conclusion, the claimed subject matter has been fully described. Reversal of the rejections under 35 U.S.C. §112 for an alleged lack of written description is thus respectfully requested.

C. Rejection of Claims Under 35 U.S.C. §112, First Paragraph - Enablement

The Examiner ejects claims 27-30 under 35 U.S.C. §112, first paragraph as allegedly not enabled. The rejected claims are directed to corn plants of the claimed variety comprising a single locus conversion. The rejected claims are directed to corn plants of variety I026458 comprising a single locus conversion. In an attempt to support the rejection, the Action cites several references alleged to show the difficulty of making male sterile or single locus converted plants. However, no basis has been given to show that these references have any relevance to *corn* plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. No showing has been made that the references apply to corn plants absent personal opinion. The

relevance of the references to the claimed invention has therefore not been established as is specifically required to establish a *prima facie* case of non-enablement.

The Examiner has further disregarded Appellants example of a conversion that has been made with a proprietary corn variety by stating that information has been left out, such as the number of crosses that were performed at each step. This is incorrect. The breeding history of the conversion that was made is given. In the breeding history, seven backcrosses are described. No steps are left out and no basis has been provided to demonstrate why this example does not demonstrate enablement for the instant variety.

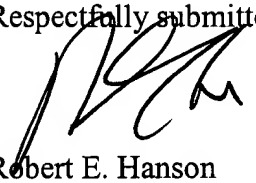
It appears that the Action has improperly placed the burden to show enablement on Appellants. The indication that the references concerning petunias, sugar beets and tomatoes apply to corn is made without any support. At the same time, the Action attempts to require Appellants to show why this is not true. Appellants respectfully note that it is the ***Office*** the bears the burden of supporting its rejections. Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko,* 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences. The current rejections are unsupported as required by the APA and contrary to the evidence submitted by Appellants.

In view of the foregoing reversal of the rejection is respectfully requested.

X. CONCLUSION

It is respectfully submitted, in light of the above, none of the pending claims lack written description. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,



Robert E. Hanson
Reg. No. 42,628
Attorney for Appellants

FULBRIGHT & JAWORSKI L.L.P
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 536-3085

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APPENDIX 1: APPEALED CLAIMS FOLLOWING ENTRY OF THE AMENDMENT UNDER 37 C.F.R. §1.116

2. A population of seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

6. The corn plant of claim 5, having:

(a) an SSR profile in accordance with the profile shown in Table 6; or

(b) an isozyme typing profile in accordance with the profile shown in Table 7.

11. The plant part of claim 10, wherein said cell is further defined as having :

(a) an SSR profile in accordance with the profile shown in Table 6; or

(b) an isozyme typing profile in accordance with the profile shown in Table 7.

14. An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.

17. A tissue culture of regenerable cells of a plant of corn variety I026458, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

18. The tissue culture of claim 17, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

19. The tissue culture of claim 18, wherein the regenerable cells comprise protoplasts or callus cells.

20. A corn plant regenerated from the tissue culture of claim 17, wherein the corn plant is capable of expressing all of the physiological and morphological characteristics of the corn variety designated I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

21. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein one or both of the first or the second parent corn plant is a plant of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228, wherein seed is allowed to form.

22. The process of claim 21, further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein the first or second inbred corn plant is a plant of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

24. Hybrid corn seed produced by the process of claim 23.

25. A hybrid corn plant produced by growing a seed produced by the process of claim 23.

26. The hybrid corn plant of claim 25, wherein the plant is a first generation (F_1) hybrid corn plant.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

29. The corn plant of claim 27, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I026458, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I026458 by crossing a plant of the corn variety I026458 with a second corn plant, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I026458.

APPENDIX 2: PENDING CLAIMS FOLLOWING ENTRY OF THE AMENDMENT UNDER 37 C.F.R. §1.116

1. A seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

2. A population of seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

5. A corn plant produced by growing a seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

6. The corn plant of claim 5, having:
   (a) an SSR profile in accordance with the profile shown in Table 6; or
   (b) an isozyme typing profile in accordance with the profile shown in Table 7.

7. A plant part of the corn plant of claim 5.

8. The plant part of claim 7, further defined as pollen.

9. The plant part of claim 7, further defined as an ovule.

10. The plant part of claim 7, further defined as a cell.

11. The plant part of claim 10, wherein said cell is further defined as having :
   (a) an SSR profile in accordance with the profile shown in Table 6; or
   (b) an isozyme typing profile in accordance with the profile shown in Table 7.

12. A seed comprising the cell of claim 10.

13. A tissue culture comprising the cell of claim 10.

14. An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.

17. A tissue culture of regenerable cells of a plant of corn variety I026458, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

18. The tissue culture of claim 17, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

19. The tissue culture of claim 18, wherein the regenerable cells comprise protoplasts or callus cells.

20. A corn plant regenerated from the tissue culture of claim 17, wherein the corn plant is capable of expressing all of the physiological and morphological characteristics of the corn variety designated I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

21. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein one or both of the first or the second parent corn plant is a plant of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228, wherein seed is allowed to form.

22. The process of claim 21, further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein the first or second inbred corn plant is a plant of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

23. The process of claim 22, wherein crossing comprises the steps of:

(a) planting the seeds of first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) preventing self pollination of at least one of the first or second inbred corn plant;

(d) allowing cross-pollination to occur between the first and second inbred corn plants; and

(e) harvesting seeds on at least one of the first or second inbred corn plants, said seeds resulting from said cross-pollination.

24. Hybrid corn seed produced by the process of claim 23.

25. A hybrid corn plant produced by growing a seed produced by the process of claim 23.

26. The hybrid corn plant of claim 25, wherein the plant is a first generation (F_1) hybrid corn plant.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

29. The corn plant of claim 27, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I026458, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I026458 by crossing a plant of the corn variety I026458 with a second corn plant, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I026458.

APPENDIX 3: PENDING CLAIMS WITHOUT ENTRY OF THE AMENDMENT UNDER 37 C.F.R. §1.116

1. A seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

2. A population of seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

4. The population of seed of claim 2, further defined as essentially free from hybrid seed.

5. A corn plant produced by growing a seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

6. The corn plant of claim 5, having:
   (a) an SSR profile in accordance with the profile shown in Table 6; or
   (b) an isozyme typing profile in accordance with the profile shown in Table 7.

7. A plant part of the corn plant of claim 5.

8. The plant part of claim 7, further defined as pollen.

9. The plant part of claim 7, further defined as an ovule.

10. The plant part of claim 7, further defined as a cell.

11. The plant part of claim 10, wherein said cell is further defined as having :
   (a) an SSR profile in accordance with the profile shown in Table 6; or

(b) an isozyme typing profile in accordance with the profile shown in Table 7.

12. A seed comprising the cell of claim 10.

13. A tissue culture comprising the cell of claim 10.

14. An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.

17. A tissue culture of regenerable cells of a plant of corn variety I026458, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

18. The tissue culture of claim 17, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

19. The tissue culture of claim 18, wherein the regenerable cells comprise protoplasts or callus cells.

20. A corn plant regenerated from the tissue culture of claim 17, wherein the corn plant is capable of expressing all of the physiological and morphological characteristics of the corn

variety designated I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

21. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein one or both of the first or the second parent corn plant is a plant of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228, wherein seed is allowed to form.

22. The process of claim 21, further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein the first or second inbred corn plant is a plant of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

23. The process of claim 22, wherein crossing comprises the steps of:

(a) planting the seeds of first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) preventing self pollination of at least one of the first or second inbred corn plant;

(d) allowing cross-pollination to occur between the first and second inbred corn plants; and

(e) harvesting seeds on at least one of the first or second inbred corn plants, said seeds resulting from said cross-pollination.

24. Hybrid corn seed produced by the process of claim 23.

25. A hybrid corn plant produced by growing a seed produced by the process of claim 23.

26. The hybrid corn plant of claim 25, wherein the plant is a first generation (F_1) hybrid corn plant.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

29. The corn plant of claim 27, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I026458, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I026458 by crossing a plant of the corn variety I026458 with a second corn plant, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I026458.

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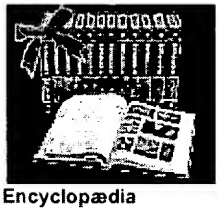

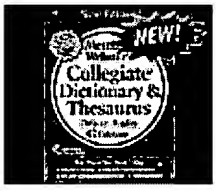

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Main Entry: **pop·u·la·tion**
Pronunciation: "pä-py&-'lA-sh&n
Function: *noun*
Etymology: Late Latin *population-, populatio,* from Latin *populus*
Date: 1612
1 a : the whole number of people or inhabitants in a country or region **b :** the total of individuals occupying an area or making up a whole **c :** the total of particles at a particular energy level -- used especially of atoms in a laser
2 : the act or process of populating
3 a : a body of persons or individuals having a quality or characteristic in common **b** (1) **:** the organisms inhabiting a particular locality (2) **:** a group of interbreeding organisms that represents the level of organization at which speciation begins
4 : a group of individual persons, objects, or items from which samples are taken for statistical measurement
- **pop·u·la·tion·al** /-shn&l, -sh&-n&l/ *adjective*

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One entry found for **homogeneous**.

Main Entry: **ho·mo·ge·neous**
Pronunciation: `-'jE-nE-&s, -ny&s`
Function: *adjective*
Etymology: Medieval Latin *homogeneus, homogenus,* from Greek *homogenEs,* from *hom-* + *genos* kind -- more at KIN
Date: 1641
1 : of the same or a similar kind or nature
2 : of uniform structure or composition throughout <a culturally *homogeneous* neighborhood>
3 : having the property that if each variable is replaced by a constant times that variable the constant can be factored out : having each term of the same degree if all variables are considered <a *homogeneous* equation>
- **ho·mo·ge·neous·ly** *adverb*
- **ho·mo·ge·neous·ness** *noun*

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One entry found for **accordance**.

Main Entry: **ac·cor·dance**
Pronunciation: &-'kor-d&n(t)s
Function: *noun*
Date: 14th century
1 : AGREEMENT, CONFORMITY <in *accordance* with a rule>
2 : the act of granting

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One entry found for **derive**.

Main Entry: **de·rive**
Pronunciation: `di-'rIv, dE-`
Function: *verb*
Inflected Form(s): **de·rived**; **de·riv·ing**
Etymology: Middle English, from Middle French *deriver,* from Latin *derivare,* literally, to draw off (water), from *de-* + *rivus* stream -- more at RUN
Date: 14th century
transitive senses
1 a : to take, receive, or obtain especially from a specified source
b : to obtain (a chemical substance) actually or theoretically from a parent substance
2 : INFER, DEDUCE
3 *archaic* **:** BRING
4 : to trace the derivation of
intransitive senses **:** to have or take origin **:** come as a derivative
synonym see SPRING
- de·riv·er *noun*

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One entry found for **protoplast**.

Main Entry: **pro·to·plast**
Pronunciation: 'prO-t&-"plast
Function: *noun*
Etymology: Middle French *protoplaste,* from Late Latin *protoplastus* first human, from Greek *prOtoplastos* first formed, from *prOt-* prot- + *plastos* formed, from *plassein* to mold -- more at PLASTER
Date: 1532
1 : one that is formed first **:** PROTOTYPE
2 : a plant cell that has had its cell wall removed; *also* **:** the nucleus, cytoplasm, and plasma membrane of a cell as distinguished from inert walls and inclusions

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